U.S. Department of Justice
Federal Bureau of Prisons
Field Acquisition Office

U.S. Armed Forces Reserve Complex
Grand Prairie, Texas 75051

July 30, 2026

RE: Request for Proposal (RFP) 15BCMS26R00000019
Comprehensive Medical Services

Dear Offeror:

Accompanying this cover letter is a solicitation package prepared by the Federal Bureau of Prisons, Field Acquisition Office, for the acquisition of Comprehensive Medical Services for FCI Williamsburg located in Salters, South Carolina. The solicitation package consists of the following:

Cover Letter
Solicitation
Attachments

In submitting proposals, offerors should consider all information provided herein. Please carefully follow all instructions located in the solicitation package concerning the content, format, and submission of the proposals.

System updates may lag policy updates. The System for Award Management (SAM) may continue to require entities to complete representations based on provisions that are not included in this solicitation. Contracting officers will rely on representations from offers based on provisions in the solicitation. Entities are not required to, nor are they able to, update their entity registration to remove these representations in SAM.

Funds are not presently available for this solicitation. No award will be made under this solicitation until funds are made available and confirmed in writing by the contracting officer. The Government reserves the right to cancel this solicitation at any time, either before or after the closing date. In the event of cancellation, the Government shall have no obligation to reimburse any responding party for any costs incurred in connection with the preparation or submission of its proposal.

All communications regarding this RFP, including any of a technical nature, must be made in writing to the Contracting Officer (CO). Questions will not be answered by telephone or in person. Please read the important instructions that are incorporated by reference in the provision

at FAR Deviation 52.212-1, Instructions to Offerors – Commercial Products and Commercial Services, and any addendum.

The CO assigned to this procurement is the undersigned. Your attention is directed to the fact that the CO is the only individual who can legally commit or obligate the Government to an expenditure of public funds should a contract result from this RFP.

Prospective Offerors are also cautioned against discussing the preparation of their offer (or any technical questions) with Government technical personnel. The circumstances of such contact, when verified, may result in non-consideration of the offer. Accordingly, all communication prior to award shall be directed to the CO, in writing, at the email address listed below.

You may e-mail any questions to J2gregory@bop.gov and BOP-ADM-FAO-CMS-S@bop.gov. We will consider all questions received and provide responses where appropriate.

Sincerely,

JEFFERSON GREGORY

Digitally signed by JEFFERSON GREGORY
Date: 2026.07.30 11:18:49 -04'00'

Contracting Officer

SOLICITATION, OFFER, AND AWARD

1. This Contract is a Rated Order under the Defense Priorities and Allocations System (DPAS) - Code of Federal Regulations - at 15 CFR 700. | RATING:

2. CONTRACT NUMBER	3. SOLICITATION NUMBER	4. TYPE OF SOLICITATION	5. DATE ISSUED	6. REQUISITION/PURCHASE NUMBER
	15BCMS26R00000019	☐ SEALED BID (IFB) INVITATION FOR BID ☒ NEGOTIATED (RFP) REQUEST FOR PROPOSAL	07/30/2026	15B31626PR000149

7. ISSUED BY
Federal Bureau of Prisons
Field Acquisition Office
U.S. Armed Forces Reserve Complex
346 Marine Forces Drive
Grand Prairie, TX 75051

CODE 15BCMS

Jefferson Gregory
(O) 202-570-8404
J2gregory@bop.gov

8. ADDRESS OFFER TO *(If other than item 7)*

NOTE: In sealed bid solicitations "offer" and "offeror" mean "bid" and "bidder".

SOLICITATION

9. Sealed offers in original and _____ copies for furnishing the supplies or services in the Schedule will be received at the place specified in item 8, or if hand carried, in the depository located in _____ until *02:00 ET* (Hour) local time *10/29/2026* (Date)

CAUTION - LATE Submissions, Modifications, and Withdrawals: See Section L, Provision Number 52.214-7 or 52.215-1. All offers are subject to all terms and conditions contained in this solicitation.

10. FOR INFORMATION CALL:	A. NAME	B. TELEPHONE *(NO COLLECT CALLS)*			C. EMAIL ADDRESS
		AREA CODE	NUMBER	EXTENSION	
	Jefferson Gregory	202	570-8404		J2gregory@bop.gov

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OFFER *(Must be fully completed by offeror)*

NOTE: Item 12 does not apply if the solicitation includes the provisions at 52.214-16, Minimum Bid Acceptance Period.

12. In compliance with the above, the undersigned agrees, if this offer is accepted within _____ calendar days *(60 calendar days unless a different period is inserted by the offeror)* from the date for receipt of offers specified above, to furnish any or all items upon which prices are offered at the price set opposite each item, delivered at the designated point(s), within the time specified in the schedule.

13. DISCOUNT FOR PROMPT PAYMENT *(See Section I, Clause Number 52.232-8)*	10 CALENDAR DAYS (%)	20 CALENDAR DAYS (%)	30 CALENDAR DAYS (%)	0 CALENDAR DAYS (%)
	0.00 %	0.00 %	0.00 %	0.00 %

14. ACKNOWLEDGEMENT OF AMENDMENTS *(The offeror acknowledges receipt of amendments to the SOLICITATION for offerors and related documents numbered and dated):*	AMENDMENT NUMBER	DATE	AMENDMENT NUMBER	DATE

15A. NAME AND ADDRESS OF OFFEROR

CODE _____ FACILITY _____

16. NAME AND TITLE OF PERSON AUTHORIZED TO SIGN OFFER *(Type or Print)*

15B. TELEPHONE NUMBER		
AREA CODE	NUMBER	EXTENSION

15C. ☐ CHECK IF REMITTANCE ADDRESS IS DIFFERENT FROM ABOVE - ENTER SUCH ADDRESS IN SCHEDULE.

17. SIGNATURE

18. OFFER DATE

AWARD *(To be completed by Government)*

19. ACCEPTED AS TO ITEMS NUMBERED	20. AMOUNT	21. ACCOUNTING AND APPROPRIATION

22. AUTHORITY FOR USING OTHER THAN FULL OPEN COMPETITION UNDER THE UNITED STATES CODE AT:
☐ 10 U.S.C. 3204(a) ( ) ☐ 41 U.S.C. 3304(a) ( )

23. SUBMIT INVOICES TO ADDRESS SHOWN IN *(4 copies unless otherwise specified)* | ITEM

25. PAYMENT WILL BE MADE BY | CODE

24. ADMINISTERED BY *(if other than Item 7)* CODE 15B316
Federal Bureau of Prisons
FCI Williamsburg
8301 HWY 521
Salters, SC 29590

26. NAME OF CONTRACTING OFFICER *(Type or print)*
Jefferson Gregory

27. UNITED STATES OF AMERICA
(Signature of Contracting Officer)

28. AWARD DATE

IMPORTANT - Award will be made on this Form, or on Standard Form 26, or by other authorized official written notice.

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Section B - Supplies or Services and Prices/Costs

CMCS-FCI WILLIAMSBURG - COMPREHENSIVE MEDICAL

Firm Fixed Price

SCHEDULE OF SUPPLIES/SERVICES

CONTINUATION SHEET

ITEM NO.	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001	Comprehensive Medical Services for FCI Williamsburg. Base Year: Effective Date of Award (EDOA) through 12 months. PSC: Q201 Base Period	12	MO	$_____	$_____
ITEM NO.	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0002	Comprehensive Medical Services for FCI Williamsburg. Option Period 1: 12 months. PSC: Q201 Unexercised Option 1	12	MO	$_____	$_____
ITEM NO.	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0003	Comprehensive Medical Services for FCI Williamsburg. Option Period 2: 12 months. PSC: Q201 Unexercised Option 2	12	MO	$_____	$_____
ITEM NO.	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0004	Comprehensive Medical Services for FCI Williamsburg. Option Period 3: 12 months. PSC: Q201 Unexercised Option 3	12	MO	$_____	$_____
ITEM NO.	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0005	Comprehensive Medical Services for FCI Williamsburg. Option Period 4: 12 months. PSC: Q201 Unexercised Option 4	12	MO	$_____	$_____
ITEM NO.	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0006	Comprehensive Medical Services for FCI Williamsburg. FAR 52.217-8 PSC: Q201 Unexercised Option 5	6	MO	$_____	$_____

Clauses By Full Text

B.01 Type of Contract

The Government contemplates award of an indefinite delivery/requirements type contract with firm-fixed unit prices, consisting of a 12-month base period and four 12-month option periods, in accordance with FAR 52.217-9, Option to Extend the Term of the Contract, and an additional extension option in accordance with FAR 52.217-8.

NAICS: 622110
Size Standard: $47M

B.02 Non-Personal Services Status

Award of this contract will result in a contractual arrangement only and shall not be construed as a personnel appointment with the BOP. The services shall not constitute an employer/employee relationship. Payments to the contractor shall be based on the provision of an end product or the accomplishment of a specific task. Results to be obtained are within the contractor's own unsupervised determination. The contractor will not be subject to Government supervision, but its efforts will be monitored for quality assurance.

Section C - Description/Specifications/Statement of Work

Clauses By Full Text

C.01 Performance Work Statement

See Attachment 2: Performance Work Statement.

Section D - Packaging and Marking

This Section Is Intentionally Left Blank

Section E - Inspection and Acceptance

Clauses By Full Text

E.01 Inspection of Services

The contractor’s efforts under this contract shall be monitored to ensure that the required output is achieved. The Government reserves the right to inspect and evaluate in a reasonable manner all services rendered during the performance of this contract. The contractor’s performance will be measured by the Government utilizing the outcome measure indicators provided in Attachment 5: Performance-Based Outcome Measures.

The Contracting Officer (CO) or designee is authorized to review by on-site survey, review of records, or by any other reasonable manner, the quality of services rendered under this contract. All records shall be subject to review by the CO or other representative of the BOP.

Payments will be denied when such service does not support the charges or if the service is deemed not necessary or appropriate. Such determinations may be made by the CO or Contracting Officer’s Representative (COR), whichever is appropriate. The provider shall furnish medical information including a narrative summary when requested by the CO or designee.

Adequate records shall be maintained to reflect accuracy with respect to medical claims submission as well as for quality and appropriateness of care. All records shall be subject to review by the CO or other delegated representatives of the BOP.

Acceptance shall occur at the site of performance for each medical service provided under this contract.

Section F - Deliveries and Performance

Clauses By Full Text

F.01 Period of Performance

Base Year: 12 Months
Option 1: 12 Months
Option 2: 12 Months
Option 3: 12 Months
Option 4: 12 Months
Option 52.217-8: Not to exceed 6 months

F.02 Commencement and Continuation of Performance

The contractor shall commence full performance of community-based services under this contract within 30 calendar days from the date of award or upon the effective date of the performance period, whichever is later. The contractor shall provide a complete security clearance investigation package for each institution-based provider within 30 calendar days from the date of award of the contract. If, at any time during contract performance, the institution-based provider is replaced, the requirement to submit the security package within 30 calendar days shall take effect from the date the replacement becomes necessary.

F.03 Quality Control Plan (QCP)

Shall be submitted to the ACO for approval before start of performance.

F.04 Specialty Care Appointments

Whenever possible, appointments for specialty care should be available within 14 calendar days from the date of referral to the specialty provider.

F.05 Medical Claims

Claims shall be submitted/invoiced within 90 calendar days after an Inmate’s discharge or outpatient encounter or other service provided under this contract.

F.06 Corrected Medical Claims

Corrected claims shall be resubmitted/re-invoiced by the contractor within 30 calendar days from the date of rejection.

F.07 Annual Billing Estimate

No later than the 10th of each month, the contractor shall initiate the billing review process by examining its records from the preceding months, including those of all subcontracted providers, to identify an estimated amount of expenditures for services rendered. Using the information gathered through this review, the contractor shall prepare and submit a written monthly estimate of Fiscal Year Obligations. The monthly estimate shall itemize projected amounts by fiscal year and by month, and shall include, at a minimum:

1. Dates of Service
2. Provider
3. Inmate Name

4. Register Number
5. Estimated Amount
6. Billed Amount

Each date of service shall be recorded on its own line. If an inmate has multiple encounters, each encounter shall be listed separately. Each monthly estimate shall address a single month only and shall not be combined with other months. Monthly estimates from prior periods shall be updated as additional services are rendered.

The contractor shall provide the written estimate to the institution no later than the 15th of each month. As invoices are paid, the contractor shall promptly remove them from subsequent estimates. The contractor shall use its best efforts to ensure all estimates submitted to the Government are accurate.

To ensure adequate funds are reserved before the fiscal year ends, the contractor shall provide early estimates for the final two months of the year. Specifically, the contractor shall submit an estimate of services anticipated for August no later than July 15th, and an estimate of services anticipated for September no later than August 15th.

F.08 Labs/Treatment/Discharge Reports

Copies of all lab, x-ray, EKG, progress notes and emergency room working notes shall also accompany the patient or be faxed immediately to the COR. A written report by the attending physician which documents the circumstances of the inpatient treatment, outpatient procedure, or other consultation shall be provided to the COR within ten business days of the inpatient discharge, outpatient procedure, or other consultation. All lab and consultations pending at time of discharge shall be faxed to the COR upon receipt but not later than ten calendar days past discharge.

Section G - Contract Administration Data

Clauses By Reference

52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)		
This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es): www.acquisition.gov		
Clause	Title	Fill-ins (if applicable)
2852.201-70	Contracting Officer's Representative (COR) (NOV 2020)	COR Name: "[Name]" Org: "[Organization]" Address: "[Address]" Phone: "[Telephone Number]" Contract: "[Contract Number]" Period: "[Period]"

Clauses By Full Text

G.01 Invoicing

Invoices shall comply with FAR Deviation 52.212-4(g). See the Attachment 2: Performance Work Statement for invoice and claims submission.

G.02 Contractor Point of Contact (POC)

The contractor shall designate a qualified POC to coordinate health services and act as the primary liaison with the COR.

G.03 Contracting Officer Responsibility

Authority to negotiate changes in the terms, conditions, or amounts cited in this contract is reserved to the CO. This responsibility may be delegated to an Administrative Contracting Officer (ACO) by the CO.

Task orders may be issued only by the CO, ACO, or an ordering official for the institution with an appropriate certificate of appointment or a delegation of authority for purchase card acquisitions. Task orders issued under the resulting contract will take the form of a BOP purchase request, purchase order, or purchase card, or purchase card acquisition form. Task orders may be mailed, faxed, or sent via email to the contractor.

G.04 Contracting Officer Representative (COR)

A COR will be designated in writing by the Contracting Officer at the time of award or after award who shall be responsible for:

- Monitoring technical progress, including surveillance and assessment of performance and issuing technical changes;
- Interpreting the scope of work;
- Technical evaluation as required;
- Technical inspection and acceptance;
- Assisting in the resolution of technical problems encountered by the service provider during contract performance;
- Monitoring funds available for obligation;
- Ensuring the task orders are issued in accordance with appropriate terms;
- Ensuring that invoices and payments are processed in a timely manner;
- Assisting in the resolution of administrative problems encountered by the service provider during the contract performance.

Section H - Special Contract Requirements

Clauses By Reference

52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)		
This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es): www.acquisition.gov		
Clause	Title	Fill-ins (if applicable)
2852.223-70	Unsafe Conditions Due to the Presence of Hazardous Material (NOV 2020)	

Clauses By Full Text

BOP DOJ-05 DEVIATION BOP-05 Security of Department Information and Systems (January 2025)

The vendor is required to complete Attachment 7 , *Federal Bureau of Prisons Vendor Cybersecurity Attestation Form,* addressing the security measures they rely upon to protect any DOJ Information and/or DOJ Information Systems for which they come into contact within the course of performing services under contract/agreement with DOJ.

The vendor shall submit the *Federal Bureau of Prisons Vendor Cybersecurity Attestation Form*, along with supporting documentation, at the time of solicitation response, annually, and when significant changes to the provided services, operating environment, or data processed occur.

DOJ-07 Prohibition On Access By Non-U.S. Citizens To DOJ IT Systems (MAR 2002)

The Department of Justice does not permit the use of Non-U.S. citizens in the performance of this contract or commitment for any position that involves access to or development of any DOJ IT system. By signing the contract or commitment document, the contractor agrees to this restriction. In those instances where other non-IT requirements contained in the contract or commitment can be met by using Non-U.S. citizens, those requirements shall be clearly described.

(End of Clause)

H.01 Organizational Conflict of Interest (FAR Deviation 9.506)

The objective of this solicitation is to satisfy the BOP's requirement for the provision of healthcare to the Inmates of the institution. A potential organizational conflict of interest may arise if the awardee is an entity which also holds or participates in a separate contract/agreement with the BOP as a medical claims adjudicator. A possible conflict of interest may exist if the awardee has dual responsibilities for the submission of medical claims for services rendered under the resulting contract and for the adjudication of those medical claims under a separate contract/agreement with the BOP.

Offers received from any firm which holds or participates in a separate contract/agreement for BOP medical claims adjudication services must address any potential organizational conflict of interest that may arise and must provide a detailed explanation of how such conflicts will be avoided. Offers received from any firm which holds or participates in

a separate contract/agreement for BOP medical claims adjudication services which fails to adequately address/resolve potential conflicts of interest will be rejected without further consideration. This limitation on the eligibility of offerors has been imposed as authorized by FAR Deviation 9.506.

H.02 Quality Control Plan (QCP)

The contractor is responsible for all management and quality control actions necessary to meet the quality standards set forth by this contract. Prior to commencing performance, the contractor shall develop and submit a quality control plan (QCP) for the institution’s approval. Once the QCP is approved by the institution, the contractor shall utilize the QCP to guide and rigorously document the implementation of the required management and quality control actions to achieve the specified output.

H.03 Contract Security/Investigative Requirements and Orientation

The employees/subcontractors of the contractor entering the institution shall meet certain security requirements to receive an institutional pass as required by Bureau of Prisons Program Statement 3732.01, dated May 22, 2018. Primary concerns are the amount of contact that may occur between the contractor and his/her employees/subcontractors with the Inmate population during the performance of the contract.

The program manager at the institution is responsible for conducting the appropriate vouchering, law enforcement checks, and ensuring that fingerprinting is completed on all contractor staff that may need access inside the confines of the secure perimeter. The institution will establish a security file that will be maintained on each of the contractor's employees /subcontractors from the beginning of the contract through its duration. The following investigative procedures will be performed:

National Crime Information Check (NCIC) check;
DOJ-99 (name check);
FD-258 (fingerprint check);
Law Enforcement Agency checks;
Vouchering of Employers;
Resume/Personal Qualifications;
OPM-329-A (Authority for Release of Information);
Complete contractor Pre-employment form;
National Agency Check and Inquiries (NACI) check (if applicable); and
Urinalysis Test (for the detection of marijuana and other drug usage).

By submitting a proposal, the contractor and its employees/subcontractors agree to complete the required documents and undergo the listed procedures. An individual who does not pass the security clearances will be unable to perform services under the contract. The final determination and completion of the security investigation procedures will be made at the sole discretion of the institution. All persons are advised that a urinalysis test for the detection of marijuana and other drug usage shall be performed. Any person(s) testing positive shall be disqualified from performing under the resulting contract. Any individual employed/subcontracted by the contractor deemed not suitable by the Bureau of Prisons requirements will not be granted access to perform services under the contract. This is a condition of the contract. The contractor must be in compliance with Department of Justice regulations at 8 CFR 274a regarding the employment of aliens. A copy of this directive is available upon the contractor's request.

In addition, each contractor employee/subcontractor must attend an orientation program and annual refresher training at the institution. The purpose of this program is to familiarize contractor employees/subcontractors with institution operations, the institution, and general rules of conduct and procedures inside the institution. Contractor employees/ subcontractors shall adhere to all institution regulations regarding conduct and performance. Contractor employees/subc

ontractors will be allowed access to the institution at the sole discretion of the Chief Executive Officer. Any individual performing under this contract may be removed if it becomes apparent his/her conduct does not reflect the conduct of that prescribed for those people performing under non-personal service contracts.

H.04 Schedule of Required Insurance

As required by FAR 52.228-5, Insurance-Work on a Government Installation, and FAR Deviation 52.237-7, Indemnification and Medical Liability Insurance, the contractor shall, at its own expense, provide and maintain during the entire performance of the resulting contract, at least the kinds and minimum amounts of insurance required as listed below:

Professional Medical Liability: See FAR Deviation 52.237-7, of this solicitation/contract.

Workers Compensation and Employers Liability: contractors are required to comply with applicable Federal and State workers compensation and occupational disease statutes.

If occupational diseases are not compensable under those statutes, they shall be covered under the employer's liability section of the insurance policy, except when contract operations are so commingled with a contractor's commercial operations that it would not be practical to require this coverage. Employer's liability coverage of at $100,000 shall be required, except in states with exclusive or monopolistic funds that do not permit workers' compensation to be written by private carriers.

Comprehensive General Liability: $500,000 per accident or occurrence for bodily injury.

However, if the contractor or subcontractor is an entity or subdivision of a State that either provides for self-insurance, and/or is limited by law to the amount of liability insurance that may be purchased, then the insurance requirements of this contract shall be fulfilled by incorporating the provisions of the applicable State law.

Before commencing work under this contract, the contractor shall certify to the CO in writing that the required insurance has been obtained. The policies evidencing required coverage shall contain an endorsement to the effect that any cancellation or any material change adversely affecting the Government's interest shall not be effective (1) for such period as the laws of the state in which this contract is to be performed, or (2) until 30 days after insurer or the contractor gives written notice to the CO, which period is longer.

The contractor shall insert the substance of this clause, including this paragraph, in subcontracts under this contract and shall require subcontractors to provide and maintain insurance required in the schedule or elsewhere in the contract. The contractor shall maintain a copy of all subcontractors' proof of required insurance and shall make copies available to the CO upon request.

Medical Malpractice: Except as provided elsewhere in this contract, the contractor shall provide and maintain medical malpractice and such other insurance during the period of this contract. Refer to FAR Deviation 52.237-7, Indemnification and Medical Liability Insurance.

If the contractor or provider who is providing services under this contract has pending litigation or administrative proceedings that may affect his/her license to practice medicine or standing as a fellow member in a professional organization, full disclosure shall be provided to the COR and
CO within five calendar days upon official notification.

If it is determined by the medical legal review that the standard of care has not been met or there is substantial evidence of negligence on the part of the contractor or contract employee/subcontractor, regardless of the final judicial decision, the provider may be unable to perform under the contract.

H.05 Contractor Training and Courtesy Privileges

Contractor training and courtesy privileges may be extended to BOP medical staff and will be limited to care and treatment of Federal Inmates to ensure continuity of care.

H.06 Quality of Patient Care/Non-Discrimination

The hospital and professional service providers will provide BOP patients under the terms of this contract the same or equal services to those provided to non-BOP patients. Professional service providers shall be provided within accepted professional standards.

The contractor agrees to make no distinction among patients under this contract on the basis of race, color, creed, national origin, or physical condition. For this contract, distinctions on the grounds of race, color, creed, national origin, or physical condition include but are not limited to the following: denying any service or benefit or availability of a facility; providing any service or benefit to a patient which is different; or if provided in a different manner or at a different time from that provided to other patients under this contract; subjecting a patient to segregation or separate treatment in any manner related to his receipt of any service; restricting a patient in any way in the enjoyment of an advantage or privilege enjoyed by others in determining whether he satisfies any admission, enrollment quota, eligibility, membership or other requirement or condition which an individual must meet in order to be provided any service or benefit; the assignment of time or places for the provision of services on the basis of race, color, creed, or national origin of the patients served.

H.07 Third Party Liability

Public Law 87-693 (42 U.S.C. 2651) provides that the United States shall be entitled to recover the reasonable value of hospital and medical care and treatment furnished or to be furnished to a person who suffers any injury or disease under circumstances indicating the Third Party's Liability involves the potential legal liability of another person for the injurer disease in question. This other person is commonly referred to as the "third party" since his/her negligent act or failure to act caused an injury or disease to the "first party" requiring medical treatment by or at the expense of the United States, the "second party."

H.08 Privacy Act Notification

This contract requires the contractor, on behalf of the institution, to provide healthcare and report requested medical record and financial information to the BOP. The BOP will use the information for financial, legal, research, and healthcare procedures.

Disclosure of this information may be made by the BOP to: fiscal intermediaries; the Office of Workers' Compensation Programs, Department of Labor; the Department of Justice for their representation of the United States; and for Congressional inquiry; quality assessment; medical audit or utilization review; billing third parties for the payment of care; analytical and evaluation studies; to federal or state agencies as required by law; and research purposes supported by the BOP.

Disclosure of the appropriate medical record information without prior consent of the subject patient may be made by you to: another provider of healthcare treating the same patient; a federal or state agency as required by law such as the reporting of communicable diseases, births, deaths, or the commission of crimes (e.g., gunshot wounds, rape, child abuse or neglect, alcohol or drug abuse, etc.); designated fiscal intermediaries; and billing third parties for the payment of care not reimbursed by the institution. The contractor must forward all other requests for information to the COR.

H.09 Authorized Users

The institution reserves the right to grant permission allowing the United States Marshals Service and Bureau of Citizenship and Immigration Services to utilize this contract. The contractor shall receive written notification from the institution when permission is granted. If approved to utilize the contract, these agencies shall be considered "optional users" with the ability to issue task orders against this contract for Federal prisoners and detainees. The contractor shall "direct bill" the applicable agency for any services that are provided under this section.

H.10 Infants Born to Inmates and Released Inmates

The BOP has the authority to pay for immediate postnatal care of a child born to a female Inmate when the BOP finds itself responsible for the cost by default (no other resource can be compelled to pay). The BOP may assume financial responsibility for the medical expenses of a child for the first three (3) days after a routine vaginal birth or up to seven (7) days for a Caesarean section. This financial responsibility may be extended for a limited time for extenuating circumstances on a case- by-case basis. The contractor shall bill the BOP according to established contract rates. In the event the infant’s medical needs exceed the BOP’s authority for financial responsibility, the contractor shall coordinate the application for financial assistance (e.g., Medicaid) for the infant. Once the BOP’s obligations as set forth in this paragraph are concluded, no further payment will be made on behalf of the Inmate’s infant child.

Offerors are advised that the BOP retains responsibility only for Inmates in the custody of the BOP. The BOP’s responsibilities, including fiscal responsibilities, end with the Inmate’s release from custody. Once released from custody, the former Inmate will become personally liable for any further medical treatment received. When an Inmate’s term of commitment expires while the Inmate is in inpatient status in a contracted facility, the BOP will use its best effort to notify the contractor in advance of the Inmate’s projected release date. In preparation of a pending release from BOP custody, the contractor shall provide planning assistance to an Inmate who requires continuing or follow-up medical care that extends beyond his or her projected release date.

Should an Inmate’s release date come while in inpatient status in a contracted hospital, the Inmate’s place of conviction and/or legal residence is outside the local area, and there are no other entities assuming custodial responsibility for the Inmate, the BOP will accept financial responsibility for the Inmate’s medical care until the BOP can satisfy its obligation provide release transportation for the Inmate.

H.11 Prompt Payment to Healthcare Providers

The Contractor shall implement and maintain payment practices consistent with customary commercial practices of healthcare payers in the surrounding community to ensure prompt payment to all healthcare providers performing services under this contract. Such payment terms shall be included as material provisions in all subcontracts/agreem ents. The Contractor shall require each healthcare provider to acknowledge, upon subcontract award, the notice provided by the Contractor regarding these payment expectations. This requirement does not create any contractual relationship between the Government and the provider.

H.12 Notice to Healthcare Providers

All healthcare providers are hereby advised that the BOP maintains no privity of contract with any party other than the prime contractor regarding performance of the above-referenced contract. Notwithstanding FAR Deviation 52.212-4(e), a subcontract or other agreement between the prime contractor and a healthcare provider is a private-party contract. As such, the BOP will not intervene in disputes between prime contractor and any subcontractor/healthcare provider on any issue, including payment disputes. All subcontractors/healthcare providers are advised that payments due from the BOP for performance under the prime contract will be paid only to the prime contractor. Accordingly, the prime contractor is responsible for remitting payments to subcontracts/healthcare providers in accordance with the terms of

the negotiated subcontract/agreement, if any. By submitting a response to the solicitation and or by accepting this award the contractor acknowledges as such, the prime contractor and subcontractors/healthcare providers should look to the remedies afforded them under any such negotiated subcontract/agreement.

If the contractor fails to make prompt payment to healthcare providers, the CO will consider any “unjustified failure(s)” by the contractor to make prompt payments to a healthcare provider when evaluating the contractor’s performance. Any unjustified failures to make prompt payments to healthcare providers will be reported in the CPARS. The Government may terminate this contract, or any part hereof, for cause in the event of any default by the prime contractor, of if the prime contractor fails to comply with any contract terms and conditions, or fails to provide the Government, upon request, with adequate assurances of future performance.

H.13 Session-Based Services – Invoice Verification (SBIV)

See Attachment 10: Session-Based Invoice Verification.

The contractor shall provide a SBIV record for each day that services are performed under this contract. Each contractor employee is responsible for accurately completing and maintaining the SBIV for the days worked and submitting it to the contractor in accordance with the contractor’s internal procedures. The contractor shall attach the applicable SBIV to each corresponding invoice submitted to the Government for payment. Failure to provide the required SBIV documentation may result in delay or withholding of payment.

H.14 Telehealth Services

All telehealth equipment and associated communication devices shall work with approved BOP telehealth communications which utilize a Webex Room. The contractor shall use a provided Webex Room URL to connect to the BOP. If the Contractor’s telehealth equipment and network environment complies with Federal IT security standards, the BOP may facilitate a direct IP connection to the provider’s telehealth connection point to facilitate IP-to-IP calls. If the direct connection option is used, the Contractor will certify compliance with all applicable Federal policies.

H. 15 Transition of Services and Continuity of Care

(a) General Requirement.
The Contractor shall use best efforts to support an orderly, efficient, and seamless transition of medical services at the expiration or termination of this contract. The contractor is expected to work collaboratively with the Government and any successor contractor to facilitate continuity of care and minimize disruption to patient services. These transition support requirements remain in effect for a period of 60 days following contract expiration or termination, unless otherwise shortened in writing by the contracting officer.

(b) Coordination with Successor Contractor.
The Contractor shall coordinate with the incoming contractor to transfer all relevant administrative, scheduling, and operational information necessary to continue medical services without interruption. This includes, but is not limited to, scheduled patient appointments, provider assignments, and related care coordination activities.

(c) Scheduled Appointments Beyond Contract Period.
The Contractor shall not cancel, reschedule, or otherwise disrupt patient appointments that are scheduled to occur beyond the contract expiration date without prior written approval of the Contracting Officer. To the maximum extent pr acticable, the Contractor shall work with the successor contractor to transfer such appointments, provided that the transfer is feasible and both contractors operate within the same or a compatible network of medical providers.

(d) Continuation of Services.
If the transfer of scheduled appointments to the successor contractor is not feasible, the Government reserves the right to require the Contractor to continue performance for those appointments. Such continued performance may be authorized through a purchase order or other appropriate contractual instrument. Services performed under this paragraph shall be provided in accordance with the rates, terms, and conditions of the most recent exercised option of this contract. The Contractor shall support and comply with such authorization to ensure uninterrupted medical care.

(e) Continuity of Care Priority.
All transition and phase-out activities shall be conducted in a manner that prioritizes patient safety, continuity of care, and compliance with all applicable laws, regulations, and standards of medical practice.

(f) No Additional Cost for Transition Cooperation.
The Contractor’s obligation to cooperate in the transition and transfer of services as described in this section shall be performed at no additional cost to the Government, except as otherwise authorized in writing by the Contracting Officer.

H. 16 Quality Assurance Plan (QAP)

The contractor shall adhere to and comply with the QAP included in this solicitation (attachment 11 - Quality Assurance Plan), including all performance monitoring, documentation, and reporting requirments contained therein.

Section I - Contract Clauses

Clauses By Reference

52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)		
This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es): www.acquisition.gov		
Clause	Title	Fill-ins (if applicable)
52.203-6 Alt I	Restrictions on Subcontractor Sales to the Government (Jun 2020) - Alternate I (Nov 2021)	
52.203-13	Contractor Code of Business Ethics and Conduct (Nov 2021)	
52.203-17	Contractor Employee Whistleblower Rights (Nov 2023)	
52.204-9	Personal Identity Verification of Contractor Personnel (Jan 2011)	
52.204-13 (DEV)	System for Award Management-Maintenance (Oct 2018) (DEVIATION NOV 2025)	
52.209-6 (DEV)	Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, Proposed for Debarment, or Voluntarily Excluded (Jan 2025) (DEVIATION NOV 2025)	
52.209-10 (DEV)	Prohibition on Contracting With Inverted Domestic Corporations (Nov 2015) (DEVIATION NOV 2025)	
52.212-4 (DEV)	Terms and Conditions-Commercial Products and Commercial Services (Nov 2023) (DEVIATION NOV 2025)	
52.216-18	Ordering (Aug 2020)	(a)From Date: "the first day of the effective contract period" (a)To Date: "the last day of the effective contract period"
52.216-19	Order Limitations (Oct 1995)	(a): "$50.00"

Clause	Title	Fill-ins (if applicable)
		(b)(1): "the estimated quantities within the current performance period as identified in Attachment 1" (b)(2): "the estimated quantities within the current performance period as identified in Attachment 1" (b)(3): "30" (d): "7"
52.216-21 (DEV)	Requirements (Oct 1995) (DEVIATION DEC 2025)	(f): "the last day of the effective contract period"
52.219-8 (DEV)	Utilization of Small Business Concerns (Jan 2025) (DEVIATION DEC 2025)	
52.219-9 (DEV)	Small Business Subcontracting Plan (Jan 2025) (DEVIATION DEC 2025)	
52.219-14 (DEV)	Limitations on Subcontracting (Oct 2022) (DEVIATION DEC 2025)	(f)(1) End of Base Term: "X"
52.219-16 (DEV)	Liquidated Damages-Subcontracting Plan (Sep 2021) (DEVIATION DEC 2025)	
52.222-3 (DEV)	Convict Labor (June 2003) (DEVIATION DEC 2025)	
52.222-35 (DEV)	Equal Opportunity for Veterans (Jun 2020) (DEVIATION DEC 2025)	
52.222-36 (DEV)	Equal Opportunity for Workers with Disabilities (Jun 2020) (DEVIATION DEC 2025)	
52.222-37 (DEV)	Employment Reports on Veterans (Jun 2020) (DEVIATION DEC 2025)	
52.222-40 (DEV)	Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (DEVIATION DEC 2025)	

Clause	Title	Fill-ins (if applicable)
52.222-50 (DEV)	Combating Trafficking in Persons (Oct 2025) (DEVIATION DEC 2025)	
52.222-54 (DEV)	Employment Eligibility Verification (Jan 2025) (DEVIATION DEC 2025)	
52.223-23 (DEV)	Sustainable Products and Services (May 2024) (DEVIATION FEB 2025)	
52.224-3	Privacy Training (Jan 2017)	
52.226-8	Encouraging Contractor Policies To Ban Text Messaging While Driving (May 2024)	
52.228-5	Insurance-Work on a Government Installation (Jan 1997)	
52.232-33	Payment by Electronic Funds Transfer-System for Award Management (Oct 2018)	
52.232-40	Providing Accelerated Payments to Small Business Subcontractors (Mar 2023)	
52.233-3 (DEV)	Protest after Award (Aug 1996) (DEVIATION NOV 2025)	
52.233-4 (DEV)	Applicable Law for Breach of Contract Claim (Oct 2004) (DEVIATION NOV 2025)	
52.237-7 (DEV)	Indemnification and Medical Liability Insurance (Jan 1997) (DEVIATION NOV 2025)	"$1,000,000.00 per occurrence/ $3,000,000.00 aggregate. However, if the contractor or subcontractor is an entity or subdivision of a State that either provides for self-insurance, and/or is limited by law to the amount of liability insurance that may be purchased, then the insurance requirements of this contract shall be fulfilled by incorporating

Clause	Title	Fill-ins (if applicable)
		the provisions of the applicable State law. "
52.240-91 (DEV)	Security Prohibitions and Exclusions (DEVIATION NOV 2025)	
52.240-93 (DEV)	Basic Safeguarding of Covered Contractor Information Systems (DEVIATION NOV 2025)	
52.244-6 (DEV)	Subcontracts for Commercial Products and Commercial Services (OCT 2025) (DEVIATION NOV 2025)	
2852.212-4	Contract Terms and Conditions, Commercial Items (FAR Deviation) (NOV 2020)	
52.222-90	Addressing DEI Discrimination by Federal Contractors	

Clauses By Full Text

52.217-8 Option to Extend Services (Nov 1999)

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor prior to the expiration of the current performance period.

(End of clause)

52.217-9 Option to Extend the Term of the Contract (Mar 2000)

(a) The Government may extend the term of this contract by written notice to the Contractor prior to the expiration of the current performance period; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 60 days before the contract expires. The preliminary notice does not commit the Government to an extension.

(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 5 years, but excludes the exercise of any option under the clause 52.217-8, Option to Extend Services, which is incorporated into the contract in full text.

(End of clause)

DOJ-01 Whistleblower Information Distribution (Oct 2021)

Within 30 days of contract award, the contractor and its subcontractors must distribute the “Whistleblower Information for Employees of DOJ Contractors, Subcontractors, Grantees, or Sub-Grantees or Personal Services Contractors” (“Whistleblower Information”) document to their employees performing work in support of the products and services delivered under this contract

(https://oig.justice.gov/sites/default/files/2020-04/NDAA-brochure.pdf). By agreeing to the terms and conditions of this contract, the prime contractor acknowledges receipt of this requirement, in accordance with 41 U.S.C. § 4712 and FAR 3.906 & 52.203-17, and commits to distribution. Within 45 days of award, the contractor must provide confirmation to the contracting officer verifying that it has distributed the whistleblower information as required.

(End of Clause)

DOJ-02 Contractor Privacy Requirements (JAN 2022)

A. Limiting Access to Privacy Act and Other Sensitive Information

(1) Privacy Act Information

In accordance with FAR 52.224-1 Privacy Act Notification (APR 1984) and FAR 52.224-2 Privacy Act (APR 1984), if this contract requires Contractor personnel to have access to information protected by the Privacy Act of 1974, the contractor is advised that the relevant DOJ system of records notices (SORNs) applicable to this Privacy Act information may be found at https://www.justice.gov/opcl/doj-systems-records.[1] Applicable SORNs published by other agencies may be accessed through those agencies' websites or by searching the Federal Digital System (FDsys) available at http://www.gpo.gov/fdsys/. SORNs may be updated at any time.

(2) Prohibition on Performing Work Outside a Government Facility/Network/Equipment

Except where use of Contractor networks, IT, other equipment, or Workplace as a Service (WaaS) is specifically authorized within this contract, the Contractor shall perform all tasks on authorized Government networks, using Government-furnished IT and other equipment and/or WaaS and Government information shall remain within the confines of authorized Government networks at all times. Any handling of Government information on Contractor networks or IT must be approved by the Senior Component Official for Privacy of the component entering into this contract. Except where remote work is specifically authorized within this contract, the Contractor shall perform all tasks described in this document at authorized Government facilities; the Contractor is prohibited from performing these tasks at or removing Government-furnished information to any other facility; and Government information shall remain within the confines of authorized Government facilities at all times. Contractors may only access classified materials on government furnished equipment in authorized government owned facilities regardless of remote work authorizations.

(3) Prior Approval Required to Hire Subcontractors

The Contractor is required to obtain the Contracting Officer's approval prior to engaging in any contractual relationship (Subcontractor) in support of this contract requiring the disclosure of information, documentary material and/or records generated under or relating to this contract. The Contractor (and any Subcontractor) is required to abide by Government and Agency guidance for protecting sensitive and proprietary information.

(4) Separation Checklist for Contractor Employees

The Contractor shall complete and submit an appropriate separation checklist to the Contracting Officer before any employee or Subcontractor employee terminates working on the contract. The Contractor must submit the separation checklist on or before the last day of employment or work on the contract. The separation checklist must verify: (1) return of any Government-furnished equipment; (2) return or proper disposition of personally identifiable information (PII)[2], in paper or electronic form, in the custody of the employee or Subcontractor employee including the sanitization of data on any computer systems or media as appropriate; and (3) termination of any technological access to the Contractor's facilities or systems that would permit the terminated employee's access to PII or other sensitive information.

In the event of adverse job actions resulting in the dismissal of a Contractor or Subcontractor employee before the separation checklist can be completed, the Prime Contractor must notify the Contracting Officer within 24 hours and confirm receipt of the notification. In the case the Contractor is unable to notify the Contracting Officer, then the Contractor should notify the Contract Officer's Representative (COR).

Contractors must complete the separation checklist with the Contracting Officer or COR by returning all Government-furnished property including, but not limited to, computer equipment, media, credentials and

passports, smart cards, mobile devices, Personal Identity Verification (PIV) cards, calling cards, and keys and terminating access to all user accounts and systems. Unless the Contracting Officer requests otherwise, the relevant Program Manager or other Key Personnel designated by the Contracting Officer or COR may facilitate the return of equipment.

B. Privacy Training, Safeguarding, and Remediation

(1) Required Security and Privacy Training for Contractors

The Contractor must ensure that all employees take appropriate privacy training, including Subcontractors who have access to PII as well as the creation, use, dissemination and/or destruction of PII at the outset of the employee's work on the contract and every year thereafter. Training must include procedures on how to properly handle PII, including heightened security requirements for the transporting or transmission of sensitive PII, and reporting requirements for a suspected breach or loss of PII. These courses, along with more information about DOJ security and training requirements for Contractors, are available at https://www.justice.gov/jmd/learndoj. The Federal Information Security Modernization Act of 2014 (FISMA) requires all individuals accessing DOJ information to complete training on records management, cybersecurity awareness, and information system privacy awareness. Contractor employees are required to sign the "Privacy Rules of Behavior," acknowledging and agreeing to abide by privacy law, policy, and certain privacy safeguards, prior to accessing DOJ information. These Rules of Behavior are made available to all new users of DOJ's computer network and to trainees at the conclusion of DOJ-OPCL-CS-0005.

The Contractor should maintain copies of certificates as a record of compliance and must submit an email notification annually to the COR verifying that all employees working under this contract have completed the required privacy and cybersecurity training.

(2) Safeguarding PII Requirements

Contractor employees must comply with DOJ Order 0904 and other guidance published to the publicly-available Office of Privacy and Civil Liberties (OPCL) Resources page[3] relating to the safeguarding of PII, including the use of additional controls to safeguard sensitive PII (e.g., the encryption of sensitive PII). This requirement flows down from the Prime Contractor to all Subcontractors and lower tiered subcontracts.

(3) Non-Disclosure Agreement Requirement

Prior to commencing work, all Contractor personnel that may have access to PII or other sensitive information shall be required to sign a Non-Disclosure Agreement (NDA) and the DOJ IT Rules of Behavior. The Non-Disclosure Agreement:

(a) prohibits the Contractor from retaining or divulging any PII or other sensitive information, or derivatives therefrom, furnished by the Government or to which they may otherwise come in contact as a result of their performance of work under the contract/task order that is otherwise not publicly available, whether or not such information has been reduced to writing; and

(b) requires the Contractor to report any loss of control, compromise, unauthorized disclosure, or unauthorized acquisition of PII or other sensitive information to the component-level or headquarters Security Operations Center within one (1) hour of discovery.

The Contractor should maintain signed copies of the NDA for all employees as a record of compliance. The Contractor should also provide copies of each employee's signed NDA to the Contracting Officer before the employee may commence work under the contract/task order.

(4) Prohibition on Use of PII in Vendor Billing and Administrative Records

The Contractor's invoicing, billing, and other financial or administrative records or databases is not authorized to regularly store or include any sensitive PII or other confidential government information that is created, obtained, or provided during the performance of the contract without the written permission of the Senior Component Official for Privacy (SCOP). It is acceptable to list the names, titles and contact information for the Contracting Officer, COR, or other personnel associated with the administration of the contract in the invoices as needed.

(5) Reporting Actual or Suspected Data Breach

Contractors must report any actual or suspected breach of PII within one hour of discovery.[4] A "breach" is an incident or occurrence that involves the loss of control, compromise, unauthorized disclosure, unauthorized acquisition, or any similar occurrence where: (1) a person other than an authorized user accesses or potentially accesses PII or (2) an authorized user accesses or potentially accesses PII for an other than authorized purpose. The report of a breach must be made to DOJ. The Contractor must cooperate with DOJ's inquiry into the incident and efforts to minimize risks to DOJ or individuals, including remediating any harm to potential victims.

(a) The Contractor must develop and maintain an internal process by which its employees and Subcontractors are trained to identify and report the breach, consistent with DOJ Instruction 0900.00.01[5], Reporting and Response Procedures for a Breach of Personally Identifiable Information.

(b) The Contractor must report any such breach by its employees or Subcontractors to the DOJ Security Operations Center (dojcert@usdoj.gov, 202-357-7000); Component-level Security Operations Center and Component-level Management Team, where appropriate; the COR; and the Contracting Officer within one (1) hour of the initial discovery.

(c) The Contractor must provide a written report to the DOJ Security Operations Center (dojcert@usdoj.gov, 202-357-7000) within 24 hours of discovery of the breach by its employees or Subcontractors. The report must contain the following information:

(i) Narrative or detailed description of the events surrounding the suspected loss or compromise of information.[6] Date, time, and location of the incident.
(ii) Amount, type, and sensitivity of information that may have been lost or compromised, accessed without authorization, etc.
(iii) Contractor's assessment of the likelihood that the information was compromised or lost and the reasons behind the assessment.[7]
(iv) Names and classification of person(s) involved, including victim, Contractor employee/Subcontractor and any witnesses.
(v) Cause of the incident and whether the company's security plan was followed and, if not, which specific provisions were not followed.[8]
(vi) Actions that have been or will be taken to minimize damage and/or mitigate further compromise.
(vii) Recommendations to prevent similar situations in the future, including whether the security plan needs to be modified in any way and whether additional training may be required.

(d) The Contractor shall provide full access and cooperation for all activities determined by the Government to be required to ensure an effective incident response, including providing all requested images, log files, and event information to facilitate rapid resolution of sensitive information incidents.

(e) At the Government's discretion, Contractor employees or Subcontractor employees may be identified as no longer eligible to access PII or to work on that contract based on their actions related to the loss or compromise of PII.

(6) Victim Remediation

At DOJ's request, the Contractor is responsible for notifying victims and providing victim remediation services in the event of a breach of PII held by the Contractor, its agents, or its Subcontractors, under this contract. Victim remediation services shall include at least 18 months of credit monitoring and, for serious or large incidents as determined by the Government, call center help desk services for the individuals whose PII was lost or compromised. When DOJ requests notification, the Department Chief Privacy and Civil Liberties Officer and SCOP will direct the Contractor on the method and content of such notification to be sent to individuals whose PII was breached. By performing this work, the Contractor agrees to full cooperation in the event of a breach. The Contractor should be self-insured to the extent necessary to handle any reasonably foreseeable breach, with another source of income, to fully cover the costs of breach response, including but not limited to victim remediation.

C. Government Records Training, Ownership, and Management

(1) Records Management Training and Compliance

(a) The Contractor must ensure that all employees and Subcontractors that have access to PII as well as to those involved in the creation, use, dissemination and/or destruction of PII take the *DOJ Records and Information Training for New Employees (RIM)* training course or another training approved by the Contracting Officer or COR. This training will be provided at the outset of the Subcontractor's/employee's work on the contract and every year thereafter. The Contractor shall maintain copies of certificates as a record of compliance and must submit an email notification annually to the COR verifying that all employees working under this contract have completed the required records management training.

(b) The Contractor agrees to comply with Federal and Agency records management policies, including those policies associated with the safeguarding of records containing PII and those covered by the Privacy Act of 1974. These policies include the preservation of all records created or received regardless of format, mode of transmission, or state of completion.

(2) Records Creation, Ownership, and Disposition

(a) The Contractor shall not create or maintain any records not specifically tied to or authorized by the contract using Government IT equipment and/or Government records or that contain Government Agency information. The Contractor shall certify, in writing, the appropriate disposition or return of all Government information at the conclusion of the contract or at a time otherwise specified in the contract. In accordance with 36 CFR 1222.32, the Contractor shall maintain and manage all Federal records created in the course of performing the contract in accordance with Federal law. Records may not be removed from the legal custody of DOJ or destroyed except in accordance with the provisions of the agency records schedules.

(b) Except as stated in the Performance Work Statement and, where applicable, the Contractor's Commercial License Agreement, the Government Agency owns the rights to all electronic information (electronic data, electronic information systems or electronic databases and all supporting documentation and associated metadata created as part of this contract. All deliverables (including all data and records) under the contract are the property of the U.S. Government and may be considered federal records, for which the Agency shall have unlimited rights to use, dispose of, or disclose such data contained therein. The Contractor must deliver sufficient technical documentation with all data deliverables to permit the agency to use the data.

(c) The Contractor shall not retain, use, sell, disseminate, or dispose of any government data/records or deliverables without the express written permission of the Contracting Officer or Contracting Officer's Representative. The Agency and its contractors are responsible for preventing the alienation or unauthorized destruction of records, including all forms of mutilation. Willful and unlawful destruction, damage or alienation of Federal records is subject to the fines and penalties imposed by 18 U.S.C. § 2701. Records may not be removed from the legal custody of the Agency or destroyed without regard to the provisions of the Agency records schedules.

D. Data Privacy and Oversight

(1) Restrictions on Testing or Training Using Real Data Containing PII

The use of real data containing PII from any source for testing or training purposes is generally prohibited. The Contractor shall use synthetic or de-identified real data for testing or training whenever feasible.

(2) Requirements for Contractor IT Systems Hosting Government Data

The Contractor is required to obtain an Authority To Operate (ATO) for any IT environment owned or controlled by the Contractor or any Subcontractor on which Government data shall reside for the purposes of IT system development, design, data migration, testing, training, maintenance, use, or disposal.

(3) Requirement to Support Privacy Compliance

(a) If this contract requires the development, maintenance or administration of information technology[9], the Contractor shall support the completion of the Initial Privacy Assessment (IPA) document, if requested by Department personnel. An IPA is the first step in a process to identify potential privacy issues and mitigate privacy risks. The IPA asks basic questions to help components assess whether additional privacy protections may be needed in designing or implementing a project[10] to mitigate privacy risks, and whether compliance work may be

needed. Upon review of the IPA, the OPCL determines whether a Privacy Impact Assessment (PIA) document and/or SORN, or modifications thereto, are required. The Contractor shall provide adequate support to complete the applicable risk assessment and PIA document in a timely manner, and shall ensure that project management plans and schedules include the IPA, PIA, and SORN (to the extent required) as milestones. Additional information on the privacy compliance process at DOJ, including IPAs, PIAs, and SORNs, is located on the DOJ OPCL website (https://dojnet.doj.gov/privacy/), including DOJ Order 0601, Privacy and Civil Liberties. The Privacy Impact Assessment Guidance and Template outline the requirements and format for the PIA.

(b) If the contract involves an IT system build or substantial development or changes to an IT system that may require privacy risk assessment and documentation, the Contractor shall provide adequate support to DOJ to ensure DOJ can complete any required assessment, and IPA, PIA, SORN, or other supporting documentation to support privacy compliance. The Contractor shall work with personnel from the program office, OPCL, the Office of the Chief Information Officer (OCIO), and the Office of Records Management and Policy to ensure that the privacy assessments and documentation are kept on schedule, that the answers to questions in the documents are thorough and complete, and that questions asked by the OPCL and other offices are answered in a timely fashion. The Contractor must ensure the completion of required PIAs and documentation of privacy controls consistent with federal law and standards, e.g. NIST 800-53, Rev. 5; and compliance with the Privacy Act of 1974, E-Government Act of 2002, Federal Information Security Modernization Act of 2014, and key OMB guidelines, e.g., OMB Circular A-130.

[1] “[T]he term ‘record’ means any item, collection, or grouping of information about an individual that is maintained by an agency, including, but not limited to, his education, financial transactions, medical history, and criminal or employment history and that contains his name, or the identifying number, symbol, or other identifying particular assigned to the individual, such as a finger or voice print or a photograph.” 5 U.S.C. § 552a(a)(4). “[T]he term ‘system of records’ means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual.” 5 U.S.C. § 552a(a)(5).
[2] As stated in FAR 52.224-3 and Office of Management and Budget (OMB) Circular A-130, Managing Federal Information as a Strategic Resource (2016), “’personally identifiable information’ means information that can be used to distinguish or trace an individual's identity, either alone or when combined with other information that is linked or linkable to a specific individual.” Regarding “sensitive PII,” “[t]he sensitivity level of the PII will depend on the context, including the purpose for which the PII is created, collected, used, processed, stored, maintained, disseminated, disclosed, or disposed. For example, the sensitivity level of a list of individuals’ names may depend on the source of the information, the other information associated with the list, the intended use of the information, the ways in which the information will be processed and shared, and the ability to access the information.” OMB Circular A-130, at App. II-2.
[3] The DOJ OPCL Resources page is available at https://www.justice.gov/opcl/resources.
[4] As stated in DOJ Instruction 0900, “Contractors must notify the Contracting Officer, the Contracting Officer’s Representative, and JSOC (or component-level SOC) within 1 hour of discovering any incidents, including breaches, consistent with this Instruction, guidance issued by the CPCLO, NIST standards and guidelines, and the US-CERT notification guidelines.”
[5] https://www.justice.gov/file/4336/download
[6] As stated in DOJ Instruction 0900, the description should include the type of information that constitutes PII; purpose for which PII is collected, maintained, and used; extent to which PII identifies a peculiarly vulnerable population; the determination of whether the information was properly encrypted or rendered partially or completely inaccessible by other means; format of PII (e.g., whether PII was structured or unstructured); length of time PII was exposed; any evidence confirming that PII is being misused or that it was never accessed.
[7] As stated in DOJ Instruction 0900, the report should include the nature of the cyber threat (*e.g.*, Advanced Persistent Threat, Zero Day Threat, data exfiltration) for cyber incidents.
[8] As stated in DOJ Instruction 0900, the report should include analysis on whether the data is accessible, usable, and intentionally targeted.
[9] As defined in 40 U.S.C. § 11101, the term “information technology” means any equipment or interconnected system or subsystem of equipment, used in the automatic acquisition, storage, analysis, evaluation, manipulation, management, movement, control, display, switching, interchange, transmission, or reception of data or information by the executive agency, if the equipment is used by the executive agency directly or is used by a contractor under a contract with the executive agency that requires the use (i) of that equipment or (ii) of that equipment to a significant extent in the performance of a service or the furnishing of a product; includes computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services), and related resources; but does not include any equipment acquired by a federal contractor incidental to a federal contract.

[10] In this instance, the term “project” is used to scope the activities (e.g., creating, collecting, using, processing, storing, maintaining, disseminating, disclosing, or disposing of information) covered by an IPA. A project is intended to be technology-neutral, and may include an information system, a digital service, an information technology, a combination thereof, or some other activity that may create potential privacy issues or privacy risks that would benefit from an IPA. The scope of a project covered by an IPA is discretionary, but components should work with their SCOP and OPCL.

(End of Clause)

DOJ-03 Personnel Security Requirements For Contractor Employees (Nov 2021)

Work performed under this contract will involve any one or more of the following: access to DOJ Information, which may include Controlled Unclassified Information (CUI), i.e., unclassified, sensitive DOJ information, and/or access to DOJ Information Technology (IT) systems, and/or unescorted access to DOJ space or facilities. Contractor employees will occupy Public Trust Positions, unless clause alternates are applied.

1. General Requirements

(a) (1) All references to “contract(or) personnel” and “contract(or) employee” in this clause means all individuals, without limitation, to include individuals employed by the contractor, team member, subcontractor, consultant, and/or independent contractor, who will have access to information of the Department of Justice (DOJ) or information that is within the custody and control of the DOJ, access to DOJ IT systems, and/or unescorted access to DOJ facilities/space in connection with the performance of this contract. “Employment” as used herein does not create nor imply an employer/employee relationship between the DOJ and contractor employees.

(b) (1) The type of security investigation required for each contractor employee will be governed by the type and risk level of information made available to the contractor employee. The contractor will not be permitted to commence performance under this contract until a sufficient number of its personnel, as determined by the Security Programs Manager (SPM), in consultation with the Contracting Officer’s Representative if one is appointed, have received the requisite security approval.

(c) Except where specifically noted otherwise, the federal government will be responsible for the cost and conduct of the investigation.

(d) The contractor shall ensure that no contractor employee commences performance prior to receipt of a written authorization from the contracting officer, COR, or the SPM that performance by the respective contractor employee is authorized.

(e) The data and other information to which the contractor may have access as a result of this contract is the property of, and/or within the custody and control of, the Department, and its disclosure to third parties is governed by various statutes and regulations, the violation of which may subject the discloser to criminal penalties.

2. Citizenship and Residency Requirements

(a) Residency Requirement. (1) Contractor employees in Public Trust positions, both U.S. citizens and non-U.S. citizens, must meet the Department’s residency requirement if they will require access to DOJ information, IT systems, or unescorted access to facilities. For three years (not necessarily consecutive years) out of the last five years immediately prior to employment under the Department contract the contractor employee must have: (i) resided in the U.S.; (ii) worked for the U.S. in a foreign country as either an employee or contractor in a federal civilian or military capacity; or, (iii) been a dependent of a federal civilian or military employee or contractor working for the U.S. in a foreign country. At the Department’s sole discretion, the residency requirement may be waived by the Department Security Officer (DSO) for contractor employees on a case-by-case basis where justified by extenuating circumstances. The residency requirement does not apply to contractor employees residing in foreign countries that are hired to work in American embassies/ consulates/missions located outside of the United States and who require access to DOJ information, IT systems, or unescorted access *provided that* an adequate background investigation can be conducted, with favorable adjudication, as determined by the DSO.

(b) Citizenship. (1) Aside from the specific exceptions set forth in Section 1.2(b)(2), for Public Trust positions, the DOJ requires that contractor employees be U.S. citizens and nationals, or lawful permanent residents seeking U.S. citizenship. Any prospective non-U.S. citizen contractor employee who requires access to DOJ information systems, DOJ information,

and/or unescorted facilities access must also have been granted a waiver as described below in paragraphs 1.2(d) and/or (e). The contractor is responsible for verifying that the non-U.S. citizens working under this contract are lawful permanent residents seeking U.S. citizenship.

(2) *Exception for Certain Non-U.S. Citizen Contractor Employees*: (i) Non-U.S. citizen expert witnesses, litigative consultants, and interpreters in rare foreign languages are not required to be lawful permanent residents seeking U.S. citizenship. However, they must be granted a waiver for access to unclassified DOJ information, whether CUI or not, DOJ IT systems, and/or unescorted facility access, as described below in paragraph 1.2(d) and (e), regardless of the duration of their duties. (ii) Non-U.S. Citizen contractor employees residing in foreign countries who are hired to work for the Department of Justice in American embassies/consulates/missions outside of the United States are not required to be lawful permanent residents seeking U.S. citizenship.

(c) Dual Citizenship. (1) U.S. citizens who hold dual citizenship with a foreign country are considered U.S. citizens within the meaning of this clause, and may be considered for, but are not entitled to, contract employment as U.S. citizens consistent with this clause. The means by which the contractor employee obtained or exercises his or her dual citizenship status will be a consideration in the Public Trust Investigation (PTI) adjudication, and/or waiver approval processes discussed in this clause.

(d) Access to DOJ Information Technology Systems. Non-U.S citizens are not authorized to access DOJ information technology (IT) systems or assist in the development, operation, management, or maintenance of DOJ IT systems, including providing IT system support, unless a waiver has been granted by the Head of the DOJ component or designee, with the prior concurrence of both the DSO and the DOJ Chief Information Officer, allowing computer access by the non-U.S. citizen. Such a waiver will be granted only in exceptional and unique circumstances on a case-by-case basis. It should be noted that the Justice Consolidated Office Network (JCON) is a sensitive DOJ IT system and any contractor employee who will need access to JCON must be a U.S. citizen or have received a waiver. In order for a waiver to be considered for approval: (1) There must be a compelling reason for using this individual as opposed to a U.S. citizen; (2) The type of personnel security vetting that has been conducted on the individual, and vetting results, that would mitigate risk; and (3) The waiver must be in the best interest of the federal government.

(e) Access to Unclassified DOJ Information and Unescorted Access to DOJ Facilities or Space. (1) Except as provided under 1.2(b)(2), non-U.S. citizens are not authorized to access DOJ information and/or unescorted access to DOJ facilities or space, unless a waiver has been granted by the DSO, allowing access by the non-U.S. citizen. Such a waiver will be granted on a case-by-case basis where justified at the discretion of the DSO.

3. Background Investigation Requirements

(a) (1) Unless otherwise stated below, all contractor personnel are subject to a Public Trust Investigation (PTI). The SPM will determine the type of investigation for each contractor employee based on the risk category (i.e., the nature of the position and degree of harm that could be caused by the individual in that position) and whether the position is long-term or short-term. The PTI risk categories are listed below.

(i) High Risk Positions. The minimum background investigation required is a Tier 4 (T4) investigation, and the five-year reinvestigation required is a Tier 4R (T4R) investigation. The 2017 version of the Standard Form (SF) 85P, Questionnaire for Public Trust Positions, is required.
(ii) Moderate Risk Positions. The minimum background investigation required is a Tier 2 (T2) investigation. The five-year reinvestigation required is a Tier 2R (T2R) investigation. The 2017 version of the SF-85P is required.
(iii) Low Risk/Non-Sensitive Positions. The minimum background investigation required for Low Risk/Non-Sensitive positions is a Tier 1 (T1) investigation and the required five-year reinvestigation is also a Tier 1 (T1) investigation. The SF 85, Questionnaire for Non-Sensitive Positions, is required.

(b) *Exception for Expert Witnesses*. Expert Witnesses, litigative consultants, and interpreters in rare foreign languages may not be subject to full background investigation requirements if alternative security requirements are approved by the DSO.

(c) *Short-Term U.S. Citizen Contractor Employees*. Other than the exception in Section 1.3(b), short-term contractor employees (6 months or less) who are U.S. citizens are not subject to a full background investigation, however, must receive an approved pre-employment background investigation waiver. The required forms to complete and submit are listed in Section 1.4(b) and (c)(2).

(d) *Long-Term U.S. Citizen Contractor Employees*. Other than the exception in Section 1.3(b), all long-term U.S. citizen employees (longer than 6 months) are subject to a full background investigation in the risk category appropriate to the position they will hold.

(e) *Non-U.S. Citizen Contractor Employees*. Other than the exception in 1.3(b), all non-U.S. citizen contractor employees regardless of performance duration (short or long term) are subject to a full background investigation in the risk category appropriate to the position they will hold.

(f) *Reciprocity*. (1) A Public Trust Investigation will be accepted under reciprocity if it meets the following guidelines: (i) the investigation is current (investigations are considered current if completed within the last five years) and favorably adjudicated, or the reinvestigation has been deferred; (ii) the investigation meets or exceeds the level of investigation required for the DOJ contractual instrument; (iii) there has been no continuous (not cumulative) break in federal contract/ service employment of two years or more; (iv) there is no derogatory information since the favorable fitness determination or adjudication that calls into question the individual's fitness based on character or conduct; and (v) the investigative record does not show conduct that is incompatible with the core duties of the new contract position. A "core duty" is a continuing responsibility that is of particular importance to the relevant covered position or the achievement of an agency's mission. Core duties will vary from position to position.

4. Background Investigation Process

(a) *e-QIP (or its successor)*. Public Trust background investigations/reinvestigations of contractor employees will be performed by the DCSA. The investigative process requires contractor employees to complete the Electronic Questionnaires for Investigations Processing (e-QIP) and provide additional information as specified in paragraph 1.4(b) below. Immediately after contract award, the contractor shall designate an employee as its "e-QIP Initiator" and provide the name of this person to the SPM. The e-QIP Initiator must have, at a minimum, a favorably adjudicated Tier 1 investigation and the appropriate DOJ security approval before being given access to e-QIP. After the e-QIP Initiator's security approval is granted, the Contractor will be configured in e-QIP as a sub-agency to DOJ. The contractor will then be responsible for initiating investigations for all contract personnel, whose previous investigation does not meet reciprocity, in e-QIP for completion of the security questionnaire form and forwarding the electronic form with the remainder of the security package to the SPM. Subject to the prior written approval of the SPM, the contractor may designate an e-QIP Initiator for each subcontractor. Subcontractor e-QIP Initiators must have, at a minimum, a favorably adjudicated Tier 1 investigation and the appropriate DOJ security approval before being provided access to e-QIP.

(b) *Additional Documentation*. (1) In addition to completing the e-QIP questionnaire (see 1.4(a), above), the contractor shall ensure that each contractor employee occupying Public Trust Positions, including short-term employees, completes and submits the following information through the contractor's Corporate Security Officer:

(i) Digital Fingerprinting/FD-258 Applicant Fingerprint Card. Two sets are required per applicant. The contractor may schedule appointments with the SPM to be digitally fingerprinted; otherwise, fingerprinting by the FBI or other law enforcement entity, as approved by the SPM, is required to ensure the identity of the person being fingerprinted and for printing quality. All pertinent information must be completed by the individual taking the fingerprints (FBI or other). Use of the physical FD-258 Applicant Fingerprint Card should only be used in extenuating circumstances.
(ii) DOJ-555 Fair Credit Reporting Act Disclosure. Authorizes DOJ to obtain one or more consumer/credit reports on the individual. This form will be required if the Component SPM determines a credit check is necessary for its Low Risk Level 1 contractor positions.
(iii) OF-306, Declaration for Federal Employment.
(iv) Foreign National Relatives or Associates Statement. This is only required if foreign national relatives or associates were not disclosed on the security questionnaire form.
(v) Self-Reporting Requirements for All Contractor Personnel. This is an acknowledgement and acceptance statement that every contractor must sign.
(vi) Additional information as may be required based on the review of the security questionnaire form.

The contractor shall review all forms/documents to ensure each is complete, accurate and meets all DOJ requirements, including applicable residency and citizenship requirements. The contractor shall resolve any issues or discrepancies with the contractor employee, including resubmission of corrected forms or documentation. Completed forms/documents shall be submitted to the SPM (or designee, which may include the COR) within five (5) calendar days after being finalized.

(c) Adjudication and Pre-Employment Background Investigation Waivers

(1) Except as set forth in this section, background investigations must be conducted and favorably adjudicated for each contractor employee prior to commencing their work on this contract. Where programmatic needs do not permit the federal government to wait for completion of the entire background investigation, a pre-employment background investigation waiver for *public trust contractors* can be granted by the SPM, in consultation with the cognizant COR. Pre-employment waivers cannot be used to circumvent delays in clearing classified contractors through the DCSA, if access to classified information is required.

(2) As directed by the SPM, the contractor shall initiate pre-employment waivers for Public Trust Positions when necessary. This may entail performing credit history checks and submission of these checks as part of the security package, including satisfactory resolution of any issues prior to submission to the federal government. A waiver will be disapproved if it develops derogatory information that cannot be resolved in the contractor employee's favor. When a waiver has been disapproved, the CO, in consultation with the SPM and COR, will determine (i) whether the contractor employee will no longer be considered for work on a DOJ contract or (ii) whether to wait for the completion and favorable adjudication of the background investigation before the contractor employee commences work on a Department contract. The pre-employment background investigation waiver requirements include:

1. Verification of citizenship (copy of a birth certificate, naturalization certificate, or U.S. passport);
2. Verification of compliance with the *DOJ Residency Requirement* of this Clause;
3. Favorable review of the security questionnaire form;
4. Favorable FBI fingerprint results;
5. Favorable credit report;
6. Favorable review of the OF-306 form, Declaration for Federal Employment;
7. Verification of the initiation of the appropriate background investigation (for long-term personnel); and
8. Receipt of the signed DOJ *Self-Reporting Requirements for All Contractor Personnel* (see Section 6, below).

(3) The investigating agency (DCSA) will provide the SPM with the results of each proposed contractor employee's Public Trust investigation. Upon receipt of the investigation and any other pertinent documents from the investigating agency, the SPM will determine whether each proposed contractor employee should be granted employment security approval.

(4) The COR will notify the contractor of the results of Public Trust background investigations as they are completed and adjudicated, including any individual who is found ineligible for employment security approval. For any individual found ineligible for employment on a Department contract, the contractor shall propose a replacement and initiate the background investigation process consistent with this clause.

5. Identity Proofing and Badging

(a) Access to DOJ Information, federally-controlled IT systems, and/or unescorted access to federally-controlled facilities or space (regardless of whether the contractor employee will be issued a DOJ PIV card or building access badge) shall be made available after each respective contractor employee has (1) met the identity proofing requirements outlined below, and (2) completed all other security requirements stated elsewhere in this contract.

(b) (1) Public Trust contractor employees must appear in person at least once before a DOJ official or an official of a trusted contract company (i.e., has a facility security clearance) who is responsible for checking two forms of identification in original form prior to commencement of work by the contractor employee and PIV card or building access badge issuance (as applicable). Approval will be documented by the DOJ official or an official of a trusted contract company. (Acceptable documents are listed in Form I 9, Employment Eligibility Verification, and at least one document must be a valid state or federal government issued picture ID).

(c) [Reserved]

(d) All contractor employees requiring unescorted access to a DOJ controlled facility or space shall comply with the PIV card or building access badge requirements outlined below:

(i) When any contractor employee enters a DOJ building for the first time, he/she shall allow one hour for security processing and the creation and issuance of a building access badge. PIV cards require additional processing time and will not likely be issued on the same day.

(ii) Building access badges shall be subject to periodic review by the contractor employee's supervisor and checked against his/her personal identification. The contractor employees shall present themselves for the issuance of renewed badges when required by the government as scheduled by the COR or his/her designee. The contractor shall notify the COR when contractor employee badges are lost, and must immediately apply for reissuance of a replacement badge. The contractor shall pay for reissued building access badges at no cost to the government. It is the contractor employee's responsibility to return badges to the COR or his/her designee when a contractor employee is dismissed, terminated or assigned to duties not within the scope of this contract.

6. Employee Reporting Requirements

(a) All contractor employees must sign the DOJ *Self-Reporting Requirements for All Contractor Personnel* statement acknowledging and accepting the DOJ requirement that they immediately self-report certain information using the Department's iReport system. The COR or SPM will provide the Self-Reporting statement as well as a list of reportable information, which varies by position sensitivity designation, to the contractor employee before commencing work under the contract. If the contractor employee does not have access to the DOJ iReport System, the COR or SPM will provide a fillable form for the contractor employee to complete and submit.

(b) The COR and SPM will review the written report and documentation and make a determination regarding continued employment on a DOJ contract.

(c) DOJ reporting requirements are in addition to the DCSA reporting requirements and the contractor's internal reporting requirements.

7. Replacement Personnel

(a) The contractor shall make every effort to avoid costs to the government for security investigations for replacement of contractor employees, and in so doing shall ensure that otherwise satisfactorily performing and physically able contractor employees remain in contract performance for the duration of the contract. The contractor shall take all necessary steps to ensure that contractor personnel who are selected for assignment to this contract are professionally qualified and personally reliable, of reputable background and sound character, and able to meet all other requirements stipulated in the contract.

(b) The fact that the government performs security investigations shall not in any manner relieve the contractor of its responsibility to ensure that all contract personnel are reliable and of reputable background and sound character. Should a security investigation conducted by the government and/or a contractor's self-report or failure to self-report render ineligible a contractor employee, the contracting officer will determine whether the contractor has violated this clause. The contracting officer may direct the contractor, at its own expense, to remove and replace any contractor personnel who fails to comply with or violates applicable requirements of this contract. Such action may be taken at the government's direction without prejudice to its rights under any other provision of this contract, including termination for default, and the contractor may be held liable, at a minimum, for all reasonable and necessary costs incurred by the government to (i) provide coverage (performance) through assignment of individuals employed by the government or third parties in those cases where absence of contractor personnel would cause either a security threat or DOJ program disruption and (ii) conduct security investigations in excess of those which would otherwise be required.

(c) Nothing in this clause shall require the contractor to bear costs involved in the conduct of security investigations for replacement of a contractor employee who separates from the contractor of his/her own accord, is incapacitated, or is deceased.

(d) The contractor shall comply with the terms and conditions set forth under this clause and assumes all liability for failure to comply. The rights and remedies conferred upon the government by this clause are in addition to all and other rights and remedies pursuant to the contract and as established by law.

(End of Clause)

DOJ-04 Federal Workplace Responses to Domestic Violence, Sexual Assault, and Stalking (DEC 2014)

(a)Department Policy on Domestic Violence, Sexual Assault, and Stalking. It is the Department's policy toenhance workplace awareness of and safety for victims of domestic violence, sexual assault, and stalking. This policy issummarized in DOJ Policy Statement 1200.02 (Policy Statement), available in full for public

viewing athttps://www.justice.gov/sites/default/files/ovw/legacy/2013/12/19/federal-workplacee-responses-to-domesticviolencesexualassault-stalking.pdfFederal-workplace-responses-to-domesticviolence-sexualassault-stalking.pdf. Vendor agrees, upon contract award, toprovide notice of this Policy Statement, including at a minimum the above-listed URL, to all of Vendor's employees andemployees of subcontractors who will be assigned to work on Department premises.
(b)Point of Contact for Victims of Domestic Violence, Sexual Assault, and Stalking. Upon contract award, theDepartment will notify contractor of the name and contact information for the Point of Contact for Victims of domesticviolence, sexual assault, and stalking for the component or components where Contractor will be performing. Contractoragrees to inform its employees and employees of subcontractors who will be assigned to work on Department premisesofthe name and contact information for the Victim Point of Contact.(End of Clause)

DOJ-08 Continuing Contract Performance During a Pandemic Influenza or other National Emergency (OCT 2007)

During a Pandemic or other emergency we understand that our contractor workforce will experience the same high levels of absenteeism as our federal employees. Although the Excusable Delays and Termination for Default clauses used in government contracts list epidemics and quarantine restrictions among the reasons to excuse delays in contract performance, we expect our contractors to make a reasonable effort to keep performance at an acceptable level during emergency periods.

The Office of Personnel Management (OPM) has provided guidance to federal managers and employees on the kinds of actions to be taken to ensure the continuity of operations during emergency periods. This guidance is also applicable to our contract workforce. Contractors are expected to have reasonable policies in place for continuing work performance, particularly those performing mission critical services, during a pandemic influenza or other emergency situation.
The types of actions a federal contractor should reasonably take to help ensure performance are:

- Encourage employees to get inoculations or follow other preventive measures as advised by the public health service.
- Contractors should cross-train workers as backup for all positions performing critical services. This is particularly important for work such as guard services where telework is not an option.
- Implement telework to the greatest extent possible in the workgroup so systems are in place to support successful remote work in an emergency.
- Communicate expectations to all employees regarding their roles and responsibilities in relation to remote work in the event of a pandemic health crisis or other emergency.
- Establish communication processes to notify employees of activation of this plan.
- Integrate pandemic health crisis response expectations into telework agreements.
- With the employee, assess requirements for working at home (supplies and equipment needed for an extended telework period). Security concerns should be considered in making equipment choices; agencies or contractors may wish to avoid use of employees' personal computers and provide them with PCs or laptops as appropriate.
- Determine how all employees who may telework will communicate with one another and with management to accomplish work.
- Practice telework regularly to ensure effectiveness.
- Make it clear that in emergency situations, employees must perform all duties assigned by management, even if they are outside usual or customary duties.
- Identify how time and attendance will be maintained.

It is the contractor's responsibility to advise the government contracting officer if they anticipate not being able to perform and to work with the Department to fill gaps as necessary. This means direct communication with the contracting

officer or in his/her absence, another responsible person in the contracting office via telephone or email messages acknowledging the contractor’s notification. The incumbent contractor is responsible for assisting the Department in estimating the adverse impacts of nonperformance and to work diligently with the Department to develop a strategy for maintaining the continuity of operations.

The Department does reserve the right in such emergency situations to use federal employees. employees of other agencies, contract support from other existing contractors, or to enter into new contracts for critical support services. Any new contracting efforts would be acquired following the guidance in the Office of federal Procurement Policy issuance "Emergency Acquisitions", May, 2007 and Subpart 18.2. Emergency Acquisition Flexibilities, of the Federal Acquisition Regulations.

(End of Clause)

Section J - List of Attachments

Identifier	Title	Number of Pages
1	Attachment 1 - Contract Pricing and Subcontract Certification - FCI Williamsburg.pdf	7
2	Attachment 2 - Performance Work Statement Including Telehealth - FCI WIlliamsburg.pdf	10
3	Attachment 3 - Computation of MS-DRG - FCI Williamsburg.pdf	1
4	Attachment 4 - Medical Care Level Classification - FCI Williamsburg.pdf	22
5	Attachment 5 - Performance-Based Outcome Measures - FCI Williamsburg.pdf	2
6	Attachment 6-A-Technical Proposal Summary Sheets - FCI Williamsburg.pdf	2
7	Attachment 6-B-Institution Based Services - FCI Williamsburg.pdf	1
8	Attachment 6-C-Telehealth Services - FCI Williamsburg.pdf	1
9	Attachment 7 - FBOP Vendor Cybersecurity Attestation - FCI Williamsburg.pdf	3
10	Attachment 8-A-List of Provider Information Requirements - FCI Williamsburg.pdf	4
11	Attachment 8-B-Informational Requirements for Medical Claims - FCI Williamsburg.pdf	2
12	Attachment 9 - BOP Formulary - FCI Williamsburg.pdf	82
13	Attachment 10 - Session-Based Invoice Verification - FCI Williamsburg.pdf	1
14	Attachment 11 - Quality Assurance Plan - FCI Williamsburg.pdf	5

Section K - Representations, Certifications and Other Statements of Offerors

Provisions By Reference

52.252-1 SOLICITATION PROVISIONS INCORPORATED BY REFERENCE (FEB 1998)

This solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text of those provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this/these address(es): www.acquisition.gov

Provision	Title	Fill-ins (if applicable)
52.203-11	Certification And Disclosure Regarding Payments to Influence Certain Federal Transactions (Sept 2024)	
52.203-18	Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements or Statements--Representation (Jan 2017)	
52.209-12	Certification Regarding Tax Matters (Oct 2025)	
52.229-11 (DEV)	Tax on Certain Foreign Procurements--Notice and Representation (Jun 2020) (DEVIATION AUG 2025)	
52.240-90 (DEV)	Security Prohibitions and Exclusions Representations and Certifications (DEVIATION NOV 2025)	

Section L - Instructions, Conditions and Notices to Offerors

Provisions By Reference

52.252-1 SOLICITATION PROVISIONS INCORPORATED BY REFERENCE (FEB 1998)		
This solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text of those provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this/these address(es): www.acquisition.gov		
Provision	Title	Fill-ins (if applicable)
52.204-7 (DEV)	System for Award Management-Registration (Nov 2024) (DEVIATION NOV 2025)	
52.212-1 (DEV)	Instructions to Offerors-Commercial Products and Commercial Services (Sep 2023) (DEVIATION NOV 2025)	
52.216-1 (DEV)	Type of Contract (Apr 1984) (DEVIATION DEC 2025)	Type of Contract: "indefinite delivery/requirements-type with firm-fixed unit prices."
52.219-4 (DEV)	Notice of Price Evaluation Preference for HUBZone Small Business Concerns (Oct 2022) (DEVIATION DEC 2025)	

Provisions By Full Text

2852.233-70 Protests Filed Directly with the Department of Justice (NOV 2020)

(a) The following definitions apply in this provision:

(1) “Agency Protest Official” (APO) means the Deciding Official for a procurement protest filed with a contracting activity of DOJ when the contracting officer will not be the Deciding Official because of the protestor's election under JAR 2833.103(b)

(2) “Deciding Official” means the official who will review and decide a procurement protest filed with the agency. The Deciding Official will be the contracting officer unless the protestor requests pursuant to JAR 2833.103(b) that the protest be decided by an individual above the level of the contracting officer, in which case the HCA will designate an APO to serve as the Deciding Official.

(3) “Interested Party” means an actual or prospective offeror whose direct economic interest would be affected by the award of a contract or by the failure to award a contract.

(b) Only interested parties may file a protest.

(c) An interested party filing a protest with the DOJ has the choice of requesting either that the Contracting Officer or the APO decide the protest.
(d) A protest filed directly with the DOJ shall:
(1) Indicate that it is a protest to DOJ.
(2) Be filed with the Contracting Officer.
(3) State whether the protestor chooses to have the Contracting Officer or the Agency Protest Official decide the protest. If the protestor is silent on this matter, the Contracting Officer will decide the protest.
(4) Indicate whether the protestor prefers to make an oral or written presentation of arguments in support of the protest to the deciding official.
(5) Include the information required by FAR 33.103(d)(2):
(i) Name, address, facsimile number and telephone number of the protestor.
(ii) Solicitation or contract number.
(iii) Detailed statement of the legal and factual grounds for the protest, to include a description of resulting prejudice to the protestor.
(iv) Copies of relevant documents.
(v) Request for a ruling by the agency.
(vi) Statement as to the form of relief requested.
(vii) All information establishing that the protestor is an interested party for the purpose of filing a protest.
(viii) All information establishing the timeliness of the protest.
(e) The decision by the APO is an alternative to a decision by the Contracting Officer. The APO will not consider appeals from the Contracting Officer's decision on an agency protest and a decision by the APO is final and not appealable.
(f) The Deciding Official may conduct a scheduling conference. The scheduling conference, if conducted, will establish deadlines for oral or written arguments in support of the agency protest and for agency officials to present information in response to the protest issues. The deciding official may hear oral arguments in support of the agency protest at the same time as the scheduling conference, depending on availability of the necessary parties.
(g) Oral conferences may take place either by telephone or in person.
(h) The protestor has only one opportunity to support or explain the substance of its protest. DOJ procedures do not provide for any discovery. The deciding official may request additional information from the agency or the protestor. The deciding official will resolve the protest through informal presentations or meetings to the maximum extent practicable.
(i) A protestor may represent itself or be represented by legal counsel. The DOJ will not reimburse the protester for any legal fees related to the agency protest.
(j) The DOJ will stay award or suspend contract performance in accordance with FAR 33.103(f), unless the contract award is justified, in writing, for urgent and compelling reasons or is determined, in writing, to be in the best interest of the Government. The justification or determination shall be approved at a level above the Contracting Officer. The stay or suspension, unless over-ridden, remains in effect until the protest is decided, dismissed, or withdrawn.
(k) The deciding official will make a best effort to issue a decision on the protest within thirty-five (35) days after the filing date. The decision shall be written, and provided to the protestor using a method that provides for evidence of receipt.
(l) The DOJ may dismiss or stay proceedings on an agency protest if a protest on the same or similar basis is filed with a forum outside DOJ.
(End of Clause)

52.212-1 (Addendum) Addendum to FAR Deviation 52.212-1 Instructions to Offerors - Commercial Products and Commercial Services

Addendum

In accordance with FAR Deviation 52-212-1, at paragraph (b) "Period for acceptance of offers," the amount of time the Offeror agrees to hold the prices in its offer is changed to 180 calendar days from the date specified for receipt of offers. Submission of each proposal revision in response to negotiations will automatically extend the acceptance period for an additional 180 days from the date of the proposal revision.

L.01 Submission Instructions

Offerors are permitted to submit only one offer in response to this solicitation. Multiple offers, alternate proposals, options for varying technical approaches, or additional pricing schemes are not permitted. If multiple offers are submitted by the

same offeror, the Government reserves the right to accept only the first offer received based on the date and time of submission or reject all offers submitted by the offeror.

Proposals shall be submitted in three separate volumes in accordance with the following requirements.

Volume 1 - Technical Proposal
Volume 2 - Past Performance Proposal
Volume 3 - Business Proposal

Offerors are required to use the following method when submitting a proposal:

A. **Electronic Proposals via e-mail.** Offerors shall submit their scanned documents of Volumes 1, 2, and 3 electronically via e-mail to J2gregory@bop.gov and a carbon copy (cc:) to BOP-ADM-FAO-CMS-S@bop.gov All documents must be in PDF format. All documents must be submitted and received within the inboxes of the email addresses listed above by the due date and time set forth in Block 9 of the Standard Form (SF) 33, page 1 of the solicitation.

B. Offers received after the proposal deadline will be processed pursuant to FAR Deviation 52.212-1(c). It remains the offerors responsibility to ensure **ALL DOCUMENTS** are in the Government's control **(recipient's inbox to the email addresses identified in paragraph A above)** by the proposal due date and time. SF33 and all amendments must be signed.

C. **PLEASE NOTE**. The following applies to all electronic submissions:
   a. Please refer to FAR Deviation 15.107(b). E-mailed proposals will not be received instantly upon transmission. Offerors must factor delivery time when submitting their proposals. As stated in paragraph B above, e-mail proposals must be received within the recipient's inbox by the proposal due date and time.
   b. The Government e-mail system can only receive documents up to 14 megabytes (MB). Therefore, the e-mail with attachments **must be less than 14 MB.**

D. The offeror is responsible to ensure all electronic documents have good resolution and are LEGIBLE. The PDF file must also be text searchable.

E. Hard copies of proposals will not be accepted.

All potential offerors are advised that this solicitation includes the provision FAR Deviation 52.212-1, *Instructions to Offerors - Commercial Products and Commercial Services*, and the provision at FAR Deviation 52.204-7, *System for Award Management*, which requires all Contractors doing business with the Federal government to be registered in the System for Award Management (SAM) database.

Offerors should include their Unique Entity ID (UEI) number in their offers. The Contracting Officer will verify registration in the SAM database prior to award by entering the potential awardee's UEI number into the SAM database. Failure to complete the registration procedures outlined in the provision noted above may result in elimination from consideration for award. Instructions for registration in SAM can be found at https://www.sam.gov.

L.02 Instructions for Preparation of Technical Proposal

The offeror's technical proposal will be an important consideration in the award of the resulting contract; therefore, it should be specific and complete. The technical proposal shall set forth in detail an offeror's conceptual approach to, and interpretation of the following: stated contract goals; proposed work plan for achieving contract objective; proposed methodology and techniques of performing the contract; and the technical resources, experience and background, as well as unique or specialized skills and expertise of both the offeror and proposed subcontractors.

The offeror's proposal should be prepared simply and economically, providing straight-forward, concise delineation of capabilities to perform satisfactorily for the contract being sought. The technical proposal should therefore be practical, legible, clear, and coherent.

Unnecessarily elaborate brochures or other presentations beyond those sufficient to present a complete and effective response to this solicitation are not desired.

The technical evaluation criteria stated within this solicitation will be used by the technical panel in evaluating proposals; therefore, each technical proposal must contain enough specificity to address each evaluation factor and the terms and conditions of the Performance Work Statement. To ensure evaluations are based solely on the merits of the submitted materials, technical proposals shall not include or reference any pricing data. Additionally, each offeror shall complete Attachment 6A: Technical Proposal Summary Sheets by Hospital Networks, 6B: Institution Based Services, 6C: Telehealth Services and include such with the offeror's technical proposal.

In addition, the offeror is required to complete Attachment 7, Federal Bureau of Prisons Vendor Cybersecurity Attestation Form, addressing the security measures they rely upon to secure any DOJ Information and/or DOJ Information Systems for which they come into contact in the course of performing services under contract with DOJ. Offerors with an existing approved Authority to Use (ATU) on file with the Federal Bureau of Prisons are not required to submit a separate Attachment 7, Federal Bureau of Prisons Vendor Cybersecurity Attestation Form for this solicitation.

Proposals which merely paraphrase the requirements of the Government's Performance Work Statement or parts thereof or use such phrases as "will comply" or "standard techniques will be employed" and/or cut and paste information from a proposed subcontractor's website will not be acceptable. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the required output.

L.03 Instructions for Preparation of Past Performance Proposal

The proposal must describe the experience of the offeror that is relevant to this contract:

- Experience providing community based inpatient/outpatient facility and professional services to a diverse Inmate population;
- Experience establishing and maintaining relationships with a large and diverse number of health care providers and/or organizations;
- Experience receiving and disseminating medical records to and from multiple health care providers.

The following information shall be included in each Past Performance Proposal:

1. A list of a total of three (3) of the offeror's most recently awarded relevant contracts with a period of performance of at least twelve (12) months. The listing shall include all items listed below:

    a. Name of contracting activity;
    b. Contract number;
    c. Date of Award;
    d. Estimated Awarded Amount;
    e. Contract Performance Period;
    f. Name, Mailing Address, telephone number, fax number, and e-mail address of the Contracting Officer, Program Manager, and Administrative Contracting Officer;
    g. Relevancy: Describe the relevance of past or current contracts including Federal, State, and local government and private that are similar in scope, complexity, and requirements to those outlined in this RFP. The discussion should include a comparison of providing healthcare services in community-based inpatient and outpatient facilities, as well as professional services, to an inmate population with a care level similar to that identified in Attachment 4: Medical Care Level Classification .

h. Provide any other information the offeror deems important to understand the past performance of the contract, the offeror’s ability to deliver quality medical services, meet schedule/performance requirements, and achieve customer satisfaction.

Offerors may be given an opportunity to address especially unfavorable reports of past performance, and the offeror's response, or lack of, will be taken into consideration. An offeror's opportunity to address reports of negative past performance information could be affected by the Government's entitlement to award without negotiations. Offerors would be well served to be aware of possible dissatisfied customers and address expected negative issues in initial proposal submissions.

For offerors with no past performance history, the offeror shall state "No Past Performance History Available."

L.04 Instructions for Preparation of Business Proposal

An offeror's business proposal shall consist of the following information:

1. Completed Attachment 1: Contract Pricing and Subcontract Certification.
2. Completed certification entered onto the provision FAR 52.209-12 Certification Regarding Tax Matters of this solicitation.
3. A brief explanation of the offeror's management structure as it relates to the performance of services under the contract.
4. A reference at a financial institution with general knowledge of the offeror's financial resources. Please include the name of the individual, name of the financial institution, address, and phone number.
5. Audited and/or certified financial statements (balance sheet, profit and loss statement) for the previous fiscal year.

Freedom of Information Act Notice

The Freedom of Information Act (FOIA) and its amendments have resulted in an increasing number of requests from outside the Government for copies of contract proposals submitted to Federal agencies. If an offeror's proposal contains information that he/she believes should be withheld from such requestors, under FOIA, on grounds that it is "trade secrets and commercial or financial information obtained from a person and privileged or confidential" [(b)(4) of the FOIA], the offeror should identify all such information so that if the proposal is ever the subject of a FOIA request, the decision to disclose or withhold can be made promptly by the responsible Federal official. If the offeror considers parts of the proposal withholdable under FOIA, the following notice should be placed on the title page:

> "Some parts of this document, as identified on individual pages, are considered by the submitter to be privileged or confidential trade secrets or commercial or financial information not subject to mandatory disclosure under the Freedom of Information Act. Material considered privileged or confidential on such grounds is contained on pages _____.”

The offeror should mark each individual item considered privileged or confidential under the FOIA with the following notice:

> "The data or information is considered confidential or privileged, and not subject to mandatory disclosure under the FOIA."

All information in the offeror's proposal which is not designated may be subject to automatic public disclosure, if it is requested under FOIA. It must be emphasized that under FOIA no information is automatically exempt from public disclosure. However, no disclosures under FOIA will be made without a careful and exacting evaluation, giving due regard

to the need for safeguarding material considered by the submitter to be privileged or confidential. The Department of Justice's policy is to withhold, whenever possible, material that is genuinely privileged or confidential.

Section M - Evaluation Factors for Award

Provisions By Reference

52.252-1 SOLICITATION PROVISIONS INCORPORATED BY REFERENCE (FEB 1998)

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Provision	Title	Fill-ins (if applicable)
52.212-2 (DEV)	Evaluation-Commercial Products and Commercial Services (Nov 2021) (DEVIATION NOV 2025)	Evaluation Factors : "Price, Technical and Past Performance. Evaluation factors other than price when combined are approximately equal to price."

Provisions By Full Text

M.01 Evaluation Procedures

Proposals will be evaluated in accordance with the criteria set forth in this solicitation. The results of the proposal evaluation will be used to determine whether an offeror's proposal will be considered for inclusion within the competitive range for the purpose of negotiations. Offerors are hereby notified that the contracting officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly evaluated proposals. Offerors are also advised that a contract award may be made without negotiation; therefore, the initial proposal should provide the Government with sufficient information to recommend a contract award without negotiations and should reflect the offeror's ability to perform at a reasonable price.

M.01.01 Technical Evaluation

The Technical Evaluation Plan will rate each offeror's proposal against technical evaluation criteria. A technical proposal deserving of an outstanding rating shall receive a higher rating than that of a mediocre proposal, as compared to the technical evaluation criteria. The technical evaluation shall be based on the documentation which supports an offeror's ability to perform in accordance with the terms and conditions of this solicitation.

M.01.02 Past Performance Evaluation

Offerors are advised that the Government will utilize information located in the Contractor Performance Assessment Reporting System (CPARS), as well as the response from the offeror regarding experience relevant to this contract to evaluate past performance.

The Government will evaluate the offeror’s past performance for the following:

a. relevancy
b. quality of services
c. timeliness of deliverables/adherence to performance schedule
d. management
e. utilization of small business and
f. regulatory compliance

Performance information will be used for both responsibility determinations and as an evaluation factor against which offerors' ratings will be compared in the determination of best value to the Government. Past performance will be rated and the Government's conclusions about the offeror's past performance will be considered in determining the relative merits of the offeror's proposal.

The Government reserves the right to use past performance information obtained from other than the sources identified by the offeror. Information may be utilized from the references listed in the proposal and other relevant references known to the BOP. The Government also reserves the right to disregard a reference as non-relevant if that reference is unable to provide an informative response. The Government reserves the right to review past performance information received by the Contracting Officer following the deadline for receipt of proposals and up to the time of award.

In cases where an offeror has no relevant past performance or past performance information is unavailable, the offeror will receive a neutral rating and will not be evaluated either favorably or unfavorably.

Evaluation of past performance will be a subjective assessment based on consideration of facts and circumstances. It will not be on absolute standards of acceptable performance. By evaluating past performance, the Government intends to consider the offeror's record of conforming to specifications and to standards of good workmanship; the offeror's adherence to contract schedules, including administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interests of the customer. This is a matter of judgment.

M.01.03 Price Evaluation

An objective price evaluation and analysis will be performed on each Offeror's price proposal. Offerors are requested to submit a separate price proposal for the base period and each individual option period, as specified in this solicitation. The evaluated price will be inclusive of the base year and all option years.

Price proposals will be evaluated to determine which proposal offers the lowest price to the Government. The offeror providing the highest discount from the Medicare rate will be considered to be offering the lowest price in each category. The offeror proposing the highest premium to the Medicare rate will be considered to be offering the highest price in each category. For other items, the offeror proposing the lowest unit price will be considered to be offering the lowest price in each category.

Offerors who vary their pricing methodology create a situation whereby the Government cannot conduct a comparative evaluation of offers in pricing aspects. Therefore, any offeror who proposes a pricing methodology in any pricing category which varies from the prescribed (e.g., proposing multiple rates within any category or proposing a differing methodology) will receive no pricing score for each such category.

M.02 Evaluation Criteria

The Government intends to make a single award to an offeror, pursuant to an affirmative determination of responsibility, whose proposal, conforming to the solicitation, is determined to be in the best interest of the Government, price and other factors considered. In this tradeoff process, non-price factors (when combined) are approximately equal to price. Technical criteria and past performance are of equal value.

Evaluation criteria to be applied to proposals received in response to this solicitation are detailed below. Offerors are advised that should the offeror's proposals be considered approximately the same or equal under non-price factors, price could be paramount in the selection decision.

M.02.01 Technical Criteria

Demonstrated approach to providing an appropriate mix of resources to deliver quality medical care to the Inmates located at the institution, while mitigating the Government's costs and security risks, as measured by the following subfactors, which are of equal importance:

1. Level of diversity of services proposed;
2. Driving distance and conditions to and from the community-based providers;
3. Accreditation status of the proposed contract facility(ies);
4. Enhancements to the basic contract requirements proposed by the offeror which will facilitate institution’s ability to conform to the BOP’s stated mission.

M.02.02 Past Performance Criteria

Subfactors 1 through 6 are listed below and are of equal importance.

1. Quality of services
2. Relevancy
3. Timeliness of deliverables/Adherence to performance schedule
4. Management
5. Utilization of Small Business
6. Regulatory Compliance

M.02.03 Price Criteria

Pricing categories are listed below in descending order of importance.

1a. Inpatient Facility Services
1b. Outpatient Facility Services
1c. Long Term Care Services
2b. Outpatient Physician Service
2a. Inpatient Physician Services
2d1. Outpatient Institution - Optometrist
2c2. Telehealth Specialties - All Others
2d2. Outpatient Institution - Physical Therapist
2c1. Tele-triage

A proportionate amount of points will be awarded to each offeror below the highest-ranked offeror in each category.

Overview

Services are required to be provided in accordance with the Performance Work Statement included in this solicitation/contract. Offerors are required to submit, as a part of their business proposal, a completed copy of the Schedule of Items and Subcontract Certification.

Pricing Methodology

Except for telehealth consultations and services based on session rate, price proposals will be calculated from benchmarks utilizing Medicare reimbursement methodologies. For each category of service to be provided, Offerors will be allowed to propose a variance from the benchmark Medicare rate in the form of a discount from or a premium to Medicare rates established by the Centers for Medicare and Medicaid Services. The rates established in the resulting contract shall not be construed as participation in the Medicare program; contract rates will merely be equated to Medicare rates of reimbursement without reductions for deductibles, copayments, or coinsurance. **When appropriate, outlier payments calculated in accordance with Medicare reimbursement methodologies shall be made in recognition of extremely costly stays.** The outlier payment shall be calculated based upon the defined benchmark and will consist of the operating portion only. This structuring of the pricing methodology is not intended to be restrictive of any offeror; offerors need only to propose that percentage discount from or premium to the Medicare benchmark rate which will reflect the desired level of payment for the category of services rendered. If during contract performance, it is determined that a necessary contract deliverable is not covered by Medicare reimbursement methodologies, a separate rate shall be negotiated for such deliverable(s).

Medicare Part A. The Medicare benchmark to be utilized for all services covered by Medicare Part A shall be the most current Basic MS-DRG Payment (i.e., Operating Federal Rate) established for Core Based Statistical Area (CBSA) 42 – South Carolina. The Basic MS-DRG calculation shall not include any provider-specific adjustments allowed under actual Medicare participation. Offerors may propose a discount from or a premium to Basic MS-DRG rates. (**Refer to Attachment 3 of this solicitation**)

Long-Term Care Facility Services (LTAC): The Medicare benchmark to be utilized for long-term care hospital services covered by Medicare Part A shall be the most current LTC-DRG payment amount (i.e., Federal Rate) established for (CBSA) 42 – South Carolina.

Medicare Part B Physician Services and Non-physician Services. The Medicare benchmark to be utilized for all physician and non-physician services covered by Medicare Part B shall be those rates established in the most current Medicare Part B Fee Schedule for Payment Locality 01, South Carolina, all counties. The benchmark charges shall be those established for participating providers. Offerors may propose a discount from or a premium to the benchmark charges.

Medicare Part B Facility Services (including hospital outpatient services and ambulatory surgical centers). The Medicare benchmark to be utilized for all facility services covered by Medicare Part B shall be the most current APC and ASC rates calculated for CBSA – 42 – South Carolina. Offerors may propose a discount from or a premium to the benchmark charges.

Estimated Quantities

Estimated quantities for the base year and all option years are detailed below. The estimated quantities provided are not a representation to the offeror/contractor that the estimated quantities will be required or ordered or that conditions affecting requirements will be stable or normal.

Inpatient and Outpatient Facility and Physician Services

FCI Williamsburg

Base Year – Effective Date of Award (EDOA) through twelve (12) months from EDOA.

Inpatient Days:	275 days (estimated)
Outpatient Visits:	1325 visits (estimated)
LTAC Days:	245 days (estimated)

Option Year 1

Inpatient Days:	275 days (estimated)
Outpatient Visits:	1325 visits (estimated)
LTAC Days:	245 days (estimated)

Option Year 2

Inpatient Days:	275 days (estimated)
Outpatient Visits:	1325 visits (estimated)
LTAC Days:	245 days (estimated)

Option Year 3

Inpatient Days:	275 days (estimated)
Outpatient Visits:	1325 visits (estimated)
LTAC Days:	245 days (estimated)

Option Year 4

Inpatient Days:	275 days (estimated)
Outpatient Visits:	1325 visits (estimated)
LTAC Days:	245 days (estimated)

Optional 6-month extension (FAR 52.217-8)

Inpatient Days:	140 days (estimated)
Outpatient Visits:	665 visits (estimated)
LTAC Days:	125 days (estimated)

Outpatient Institution Services

Estimated quantities shall remain constant for the 12-month base year and (4) 12-month options. All option periods including 52.217-8 are detailed below. For Medicare-based services, duration of visits is listed for informational purposes only, as contracted rates will be based upon the Medicare allowable per procedure performed. Session-based services shall be paid based upon the provision of defined sessions.

Note: Session-priced items which exceed the established session or are less than a full session shall be pro-rated to the nearest quarter hour.

12-Month Base Year and (4) 12-Month Options

	Session Duration Hours (approximate)	Session Quantity per Contract Year (estimated)
Optometrist	8	48
Physical Therapist	8	24

52.217-8 Optional 6-Month Extension

	Session Duration Hours (approximate)	Session Quantity per 6-Month Extension (estimated)
Optometrist	8	24
Physical Therapist	8	12

Telehealth Services

Estimated quantities shall remain constant for the 12-month base year and (4) 12-month options. All option periods including 52.217-8 are detailed below. Payment for telehealth services shall reflect the contracted rate and actual usage.

12-Month Base Year and (4) 12-Month Options

Telehealth Specialty	Consultation Quantity per Contract Year (approximate)
Tele-triage	25
Cardiologist	80
Dermatologist	25
Endocrinologist	40
Gastroenterologist	5
General Surgeon	5
Neurologist	5
Nephrologist	25
Pulmonologist	5
Rheumatologist	65
Urologist	5
Infectious Disease Specialist	5

52.217-8 Optional 6-Month Extension

Telehealth Specialty	Consultation Quantity per Contract Year (approximate)
Tele-triage	12
Cardiologist	40
Dermatologist	12
Endocrinologist	20
Gastroenterologist	3
General Surgeon	3
Neurologist	3
Nephrologist	12
Pulmonologist	3
Rheumatologist	32
Urologist	3
Infectious Disease Specialist	3

Offerors shall complete the following Schedule of Items. All proposed pricing will be evaluated in accordance with Federal Acquisition Regulation (FAR) Deviation 52.212-2, *Evaluation - Commercial Products and Commercial Services*, as outlines in the solicitation.

Base Year

Effective Date of Award (EDOA) through twelve (12) months from EDOA.

1a. Inpatient Facility Services: - __ Discount or + ___ Premium to Medicare Part A
1b. Outpatient Facility Services: - __ Discount or + ___ Premium to Medicare Part B
1c. LTAC Facility: - __ Discount or + ___ Premium to Medicare Part A
2a. Inpatient Physician Services: - __ Discount or + ___ Premium to Medicare Part B
2b. Outpatient Physician Services: - __ Discount or + ___ Premium to Medicare Part B
2c. Telehealth Services:
2c1: Tele-Triage: $_____ per consultation
2c2. Telehealth Specialties - All Other: $_____ per consultation
2d. Outpatient Institution Services:
2d1. Optometrist: $_____ per eight (8) hour session
2d2. Physical Therapist: $_____ per eight (8) hour session

NOTE: IF OFFERING A VARIANCE FROM THE BENCHMARK MEDICARE RATE, INSERT APPLICABLE "-/+" PERCENTAGE. IF NO VARIANCE, ENTER "0".

Option Year 1

1a. Inpatient Facility Services: - __ Discount or + ___ Premium to Medicare Part A
1b. Outpatient Facility Services: - __ Discount or + ___ Premium to Medicare Part B
1c. LTAC Facility: - __ Discount or + ___ Premium to Medicare Part A
2a. Inpatient Physician Services: - __ Discount or + ___ Premium to Medicare Part B
2b. Outpatient Physician Services: - __ Discount or + ___ Premium to Medicare Part B
2c. Telehealth Services:
2c1: Tele-Triage: $_____ per consultation
2c2. Telehealth Specialties - All Other: $_____ per consultation
2d. Outpatient Institution Services:
2d1. Optometrist: $_____ per eight (8) hour session
2d2. Physical Therapist: $_____ per eight (8) hour session

NOTE: IF OFFERING A VARIANCE FROM THE BENCHMARK MEDICARE RATE, INSERT APPLICABLE "-/+" PERCENTAGE. IF NO VARIANCE, ENTER "0".

Option Year 2

1a. Inpatient Facility Services: - __ Discount or + ___ Premium to Medicare Part A
1b. Outpatient Facility Services: - __ Discount or + ___ Premium to Medicare Part B
1c. LTAC Facility: - __ Discount or + ___ Premium to Medicare Part A
2a. Inpatient Physician Services: - __ Discount or + ___ Premium to Medicare Part B
2b. Outpatient Physician Services: - __ Discount or + ___ Premium to Medicare Part B
2c. Telehealth Services:
2c1: Tele-Triage: $_____ per consultation
2c2. Telehealth Specialties - All Other: $_____ per consultation
2d. Outpatient Institution Services:
2d1. Optometrist: $_____ per eight (8) hour session
2d2. Physical Therapist: $_____ per eight (8) hour session

NOTE: IF OFFERING A VARIANCE FROM THE BENCHMARK MEDICARE RATE, INSERT APPLICABLE "-/+" PERCENTAGE. IF NO VARIANCE, ENTER "0".

Option Year 3

1a. Inpatient Facility Services: - __ Discount or + ___ Premium to Medicare Part A
1b. Outpatient Facility Services: - __ Discount or + ___ Premium to Medicare Part B
1c. LTAC Facility: - __ Discount or + ___ Premium to Medicare Part A
2a. Inpatient Physician Services: - __ Discount or + ___ Premium to Medicare Part B
2b. Outpatient Physician Services: - __ Discount or + ___ Premium to Medicare Part B
2c. Telehealth Services:
2c1: Tele-Triage: $_____ per consultation
2c2. Telehealth Specialties - All Other: $_____ per consultation
2d. Outpatient Institution Services:
2d1. Optometrist: $_____ per eight (8) hour session
2d2. Physical Therapist: $_____ per eight (8) hour session

NOTE: IF OFFERING A VARIANCE FROM THE BENCHMARK MEDICARE RATE, INSERT APPLICABLE "-/+" PERCENTAGE. IF NO VARIANCE, ENTER "0".

Option Year 4

1a. Inpatient Facility Services: - __ Discount or + ___ Premium to Medicare Part A
1b. Outpatient Facility Services: - __ Discount or + ___ Premium to Medicare Part B
1c. LTAC Facility: - __ Discount or + ___ Premium to Medicare Part A
2a. Inpatient Physician Services: - __ Discount or + ___ Premium to Medicare Part B
2b. Outpatient Physician Services: - __ Discount or + ___ Premium to Medicare Part B
2c. Telehealth Services:
2c1: Tele-Triage: $_____ per consultation
2c2. Telehealth Specialties - All Other: $_____ per consultation
2d. Outpatient Institution Services:
2d1. Optometrist: $_____ per eight (8) hour session
2d2. Physical Therapist: $_____ per eight (8) hour session

NOTE: IF OFFERING A VARIANCE FROM THE BENCHMARK MEDICARE RATE, INSERT APPLICABLE "-/+" PERCENTAGE. IF NO VARIANCE, ENTER "0"

Option to Extend Services as Authorized by FAR 52.217-8

1a. Inpatient Facility Services: - __ Discount or + ___ Premium to Medicare Part A
1b. Outpatient Facility Services: - __ Discount or + ___ Premium to Medicare Part B
1c. LTAC Facility: - __ Discount or + ___ Premium to Medicare Part A
2a. Inpatient Physician Services: - __ Discount or + ___ Premium to Medicare Part B
2b. Outpatient Physician Services: - __ Discount or + ___ Premium to Medicare Part B
2c. Telehealth Services:
2c1: Tele-Triage: $_____ per consultation
2c2. Telehealth Specialties - All Other: $_____ per consultation
2d. Outpatient Institution Services:
2d1. Optometrist: $_____ per eight (8) hour session
2d2. Physical Therapist: $_____ per eight (8) hour session

NOTE: IF OFFERING A VARIANCE FROM THE BENCHMARK MEDICARE RATE, INSERT APPLICABLE "-/+" PERCENTAGE. IF NO VARIANCE, ENTER "0".

All offerors are hereby advised the successful offeror's unit pricing (to include discount percentage from or premium percentage to the benchmark Medicare rate) for the base year and all option years is public information in accordance with FAR Deviation 15.207-2. Accordingly, all successful unit pricing will be released to unsuccessful offerors with the notification of award as well as to the public when requested. Any party who objects to the release of their own unit pricing information, should they be awarded a contract in response to this solicitation, should not submit a proposal in response to the solicitation.

Subcontract Certification

This contract { } does or { } does not, provide for subcontracting possibilities.

If answer is in the affirmative, offeror { } will, submit a subcontracting plan in accordance with the requirements of FAR Deviation 52.219-9.

Offerors are strongly encouraged to consult the following link to obtain assistance with subcontracting opportunities: https://www.sba.gov/federal-contracting/counseling-help/commercial-market-representatives

I. Background

The Federal Bureau of Prisons (BOP) was established in 1930 to provide more progressive and humane care for Federal Inmates, to professionalize the prison service, and to ensure consistent and centralized administration. Today, the BOP is responsible for the custody and care of approximately 153,874 federal Inmates. The Federal prison system is a nationwide system of prisons and detention facilities for the incarceration of Inmates who have been sentenced to imprisonment for Federal crimes and the detention of individuals awaiting trial in Federal court. It is the mission of the BOP to protect society by confining Inmates in the controlled environments of prisons and community-based facilities that are safe, humane, cost-efficient, and appropriately secure, and that provide work and other self-improvement opportunities to assist Inmates in becoming law-abiding citizens.

As an agency under the Executive Branch of the United States Government, the BOP receives an annual appropriation of funds to accomplish its assigned mission. The public trust demands that this annual appropriation be prudently managed. Thus, dollars spent to maintain the health of the Inmate population must reflect the agency's best efforts to obtain cost-effective healthcare consistent with community standards.

In meeting the healthcare needs of a growing Inmate population, the BOP provides essential medical, dental, and mental health services to Federal Inmates with BOP resources. When a medical need arises which cannot be provided within prison walls by BOP resources, referrals are then made to community-based providers. It is the goal of this solicitation to establish a contractual agreement that will provide necessary professional and facility services for both inpatient admissions and outpatient encounters.

The Field Acquisition Office intends to make a single award to a responsible entity for the provision of Comprehensive Medical Services as set forth in this solicitation/contract. The Federal Correctional Institution (FCI) (hereinafter referred to as "institution(s)") is located in Salters, South Carolina and includes the following institutions:

- FCI Williamsburg – Male Inmates, Care Level 2
- SPC Williamsburg – Make Inmates, Care Level 2

Presently, the institution is identified as Care Level 2 BOP facility. This medical classification indicates institutions that house inmates having more complex medical conditions. They require more than monthly encounters with primary or specialty clinical consultants. They require frequent clinical contact to maintain control/ stability of their conditions. Criteria for categorizing an Inmate in the Care Level 2 category is included as **Attachment 4: Medical Care Level Classification**. Despite this description of the general health of the Inmate population, the need for Inmate healthcare may arise at varying levels of complexity. Classification and designation of Inmates is the sole responsibility of the BOP and may change at any time without consideration to the contractor.

A mileage restriction has not been placed on this acquisition. The BOP reserves the right to determine if the proposed driving distances/conditions to community-based providers pose an unacceptable cost or security risk and to find such offers unacceptable.

II. Statement of Output

Within this Performance Work Statement (PWS), necessary services are described in terms of output rather than specific task assignments. The BOP desires to make an award to the offeror who can provide the best value, considering the diversity of available services and price, among other criteria. Therefore, the Government may award any or all line items, may withhold award of any or all line items, or may award to an offeror who proposes less than the full complement of services contained in this solicitation. Accordingly, output items 1 and 2 are optional deliverables while output items 3, 4, and 5 are applicable to all services provided. Offerors are encouraged to submit comprehensive proposals committing to provide all output listed in the solicitation. Offerors who propose less comprehensive approaches will be evaluated accordingly.

Output #1: Provide inpatient and outpatient facility services which conform to community standards and all local, state and Federal laws and regulations applicable to the delivery of healthcare to members of the general public. (Cross-reference pricing categories 1a, 1b and 1 c.)

Output #2: Provide professional services which conform to community standards and all local, state and Federal laws and regulations applicable to the delivery of healthcare to members of the general public. (Cross-reference pricing categories 2a, 2b, 2c1, 2c2, 2d1, and 2d2)

Output #3: Submit properly-priced invoices for services rendered.

Output #4: Manage medical record information in a manner which promotes continuity of care while observing restrictions on the release of information.

Output #5: Maintain open avenues of communication, facilitating the exchange of information between the contract provider, contract facility, and the Government regarding the contract services.

III. Specific Requirements

Output #1: Provide inpatient and outpatient facility services which conform to community standards and all local, state and Federal laws and regulations applicable to the delivery of healthcare to members of the general public.

Output #1 is an optional deliverable. However, if the offeror proposes to provide these services, the following minimum requirements apply. Throughout the performance of this contract, the contractor shall not utilize any provider that appears in the List of Excluded Individuals/Entities (LEIE) maintained by the U.S. Department of Health & Human Services.

If proposed, the contractor shall provide facility services on an as-needed basis in a manner which adheres to community standards of quality and cost-effective medical care. The services required to satisfy Output #1 may include inpatient facility and outpatient facility, including emergency room services. Inpatient visits for non-emergency services shall require private room accommodations with available space for up to three armed or unarmed guards per Inmate.

It is the institution's preference to obtain the services of facilities that are accredited by The Joint Commission. Offerors utilizing facilities which maintain accreditation by The Joint Commission shall submit a copy of the current accreditation certificate as part of the offeror's technical proposal. If an offeror intends to utilize a facility which is accredited or certified by any other recognized professional accrediting body, the offeror shall submit documentation validating this accreditation or certification as a part of its proposal.

The offeror's technical proposal shall discuss in detail the diversity of services, as well as the proximity of facility providers to the institution, that it is capable of providing to achieve Output #1.

Output #2: Provide professional services which conform to community standards and all local, state, and Federal laws and regulations applicable to the delivery of healthcare to members of the general public.

Output #2 is an optional deliverable. However, if the offeror proposes to provide these services, the following minimum requirements shall apply. Throughout the performance of this contract, the contractor shall not utilize any provider that appears in the LEIE.

Community-Based Services

Professional services resulting from a BOP referral are necessary to be performed in a community-based setting (e.g., hospital facility, surgical center, physician's office, etc.). If proposed, the contractor shall provide the services of professional medical staff who have appropriate educational qualification, experience, licensure, and board certification (where required) to achieve Output #2. This output specifically *excludes* the provision of radiological interpretations of BOP-provided films, images, or other media.

The following specialties may be provided via telehealth, contingent upon an acceptable offer. The BOP reserves the right to award all, some or none of the following telehealth services:

Tele-triage	Neurologist
Cardiologist	Nephrologist
Dermatologist	Pulmonologist
Endocrinologist	Rheumatologist
Gastroenterologist	Urologist
General Surgeon	Infectious Disease Specialist

It is the institutions' preference to obtain telehealth services from providers that maintain privileges within facilities identified within Output #1.

If the contractor performs telehealth services, the following minimum requirements shall apply:

Telehealth Services: The contractor shall provide Telehealth services during the hours of 7:00 am through 3:00 pm. The contractor shall provide timely, secure, and clinically appropriate Telehealth services resulting in completed virtual encounters, accurate documentation, and patient care instructions.

Teletriage Services: Teletriage services shall be provided 24 hours per day, 7 days per week, including weekends and holidays ensuring continuous access without interruption. The contractor shall perform clinical assessment and acuity determination, producing accurate triage determinations, timely escalation of emergent cases, and documented care recommendations.

If requested by the Contracting Officer (CO), the contractor shall be required to document primary source verification of the credentials for each provider including: current license from the appropriate State Board of Medical Examiners, education from professional schools or universities, evidence of completion of internships and/or residences as appropriate.

With the exception of Teletriage Services, appointments for specialty care should be available within 14 calendar days from the date of referral to the specialty provider whenever possible. This practice promotes the safety and security of the Federal prisoner, the escorting correctional staff, and the general public. The medical urgency of any referral must receive consideration in the scheduling and delivery of professional services.

For prescriptions to be filled by the institution's pharmacy, contract providers shall only prescribe pharmaceutical drugs that are listed in the approved **Attachment 9 - BOP Formulary**. Updated BOP Formularies will be posted to bop.gov. Requests for exemptions shall be submitted to the Contracting Officer's Representative (COR), who shall obtain the required approvals. As part of the Discharge Instructions, the issuance of sample medication to any Federal Inmate shall be prohibited.

In the event it becomes necessary for the Government to cancel a scheduled visit, the institution will provide the contract provider with 48-hour written or verbal notice prior to canceling a visit. However, certain circumstances beyond the control of the institution (e.g., fog or other Acts of God, institution disturbances, etc.) may dictate the cancellation of a scheduled visit with less than 48 hours written or verbal notice.

The offeror's technical proposal shall discuss in detail the diversity of services, as well as the proximity of professional providers to the institution.

Institution-Based Services

As an additional tool to satisfy Output #2, professional services may be performed within the confines of the institution. If the resulting contract does not provide for telehealth consultation or all the outpatient institution service clinics listed, the institution reserves the right to pursue such contracts. The institution also reserves the right to determine the manner of an Inmate's referral, i.e., via outpatient institution service clinic, via community-based referral, via telehealth consult, or any other method the institution determines to be reasonable and appropriate.

If the contractor performs outpatient institution service specialty clinics at the institution, the following minimum requirements shall apply. Contract services shall be provided outpatient institution service within the Health Services Department of the institution. Consultations shall be limited to the chief complaint on the BOP consultation form.

Services shall include diagnosis and treatment of medical conditions with appropriate referral, if necessary, to a specialist at the contract medical facility. Scheduling of clinics shall be subject to the mutual agreement of the institution and the contract provider. The institution will schedule Inmates for outpatient institution service clinics. Providers performing institution-based services shall hold a current, unrestricted license to practice medicine in one or more of the United States. Providers performing these services shall apply for clinical privileges at the institution. All clinical privileges shall be appropriate to the qualifications of the provider and the resources of the facility where care is provided. Any clinical privileges granted due to the award of this contract shall be contingent upon the continuation of this contract and upon the physician's continued affiliation with the contractor or any subcontractor. Continuation of privileges at the institution shall be at the sole discretion of the institution. Non-physician providers shall hold a current, unrestricted license to practice

medicine in one or more of the United States.

The following specialty clinics/sessions may be conducted at the institution, contingent upon an acceptable offer. The BOP reserves the right to award all, some or none of the following outpatient institution service clinics:

Optometry
Physical Therapist

In the event it becomes necessary for the Government to cancel a scheduled visit, the institution will provide the contract provider with 48-hour written or verbal notice prior to canceling a visit. However, certain circumstances beyond the control of the institution (e.g., fog or other Acts of God, institution disturbances, etc.) may dictate the cancellation of a scheduled visit with less than 48 hours written or verbal notice. In the event it becomes necessary for the contract provider to cancel a scheduled visit, the contractor may provide qualified replacement professional staff or may reschedule a mutually agreed upon replacement session. Prior to utilizing replacement staff, the contractor must obtain preliminary clearance from the CO or COR, in accordance with the security and privileging requirements of this contract.

All contract personnel providing services within the confines of the institution shall have a complete background investigation conducted in accordance with BOP Program Statement 3732.01, "BOP Identifications and Background Investigation." All contract providers and other applicable staff who will enter the institution to perform services on a recurring basis shall be required to attend a four-hour institution orientation course held at the institution or a mutually acceptable site. A "refresher" orientation must be completed annually. The contractor's costs for contract staff to attend this training shall be the responsibility of the contractor. The CO or COR will be responsible for scheduling training for all applicable contract staff.

Output #3: Submit properly-priced invoices for services rendered.

Overview. Upon completion of a treatment encounter, the contractor shall prepare and submit proper invoices for services rendered under this contract. For the purpose of this contract, a specific definition for what documentation constitutes an invoice is provided below. A proper invoice shall include the information specified in FAR Deviation 52.212-4, Contract Terms and Conditions - Commercial Products and Commercial 15.Services, paragraph (g). Services shall be invoiced in accordance with the terms and conditions of the contract, including the payment rate structures specified in the contract.

Invoice/Medical Claims Adjudication. The institution will employ a process of invoice/medical claims adjudication to ensure, at a minimum, that the services billed by the contractor were properly authorized and ordered by the institution, are appropriately coded in compliance with Medicare coding policies (where applicable), are properly priced in accordance with the terms and conditions of the contract, and do not represent duplicate billings for payments already made. In addition, the institution may utilize the services of a third-party medical claims adjudicator to review medical claims submitted by the contractor under this contract. When requested by the institution, the contractor shall comply with all reasonable requests for additional invoice/medical claim/medical record documentation. All invoice payments shall be made by the institution and any disagreements regarding the paid amount of any invoice shall be resolved directly with the institution.

Invoice Definitions.

Line Items 1a - Inpatient Facility Services, 1b - Outpatient Facility Services, 1c - Long Term Care Services, 2a - Inpatient Physician Services, and 2b - Outpatient Physician Services: At the outset of this contract, an invoice for services rendered under Line Items 1a, 1b, 1c, 2a, and 2b shall be a paper version of an invoice containing not more than 50 individual medical claims. Each invoice shall be supported with paper copies of Universal Billing (UB) 04 forms or Centers for Medicare and Medicaid Services (CMS) 1500 forms, as applicable, for each medical claim included in the invoice.

Following written notification to the contractor by the CO that a third-party medical claims adjudication service will be utilized by the institution, an invoice for services rendered under the Line Items identified in the previous paragraph shall be a paper invoice. Each invoice shall not detail more than 50 individual medical claims which have been electronically transmitted to the BOP's medical claims adjudicator via American National Standards Institute (ANSI) 837 format that also conforms to Medicare and Health Insurance Portability and Accountability Act of 1996 (HIPAA) electronic billing standards. For each medical claim included on the invoice, the contractor shall reference, at a minimum, the following information: Task Order number, Inmate name, register number, date of service, provider of service name and NPI number, billed code, and contract amount billed. Medical claims detailed in the invoice shall be listed first in descending order by the Task Order number, second in alphabetic order by the Inmate's last name, and third by ascending date of service (i.e., earliest to latest) when more than one medical claim is present for the same Inmate within the same invoice. A copy of the invoice including the same fields listed above will also be provided to the institution in Microsoft Excel or comma-separated values (CSV) format. The electronic copy of the invoice shall be submitted to the institution using an encrypted email service.

If the contractor's proposal encompasses the provision of oral surgery and/or dental procedures, only those medical claims which represent adjunctive dental care will be submitted by the contractor to the medical claims adjudication contractor for processing. Oral surgery and/or dental procedures which are not considered to be adjunctive dental care will be submitted to the institution for verification.

The contractor shall not submit a medical claim for processing that the contractor knows or has reason to believe contains inaccurate, incomplete, or misleading information. Additionally, the contractor shall only submit Current Procedural Terminology (CPT)/Healthcare Common Procedure Coding System (HCPCS) provided by medical service providers. Medical claims which contain inaccurate, incomplete or misleading information shall be held by the contractor and not submitted until such time as all lines are deemed to be accurate and complete. At that time, the contractor may proceed with submitting the medical claim for processing and invoicing the institution for all services represented by that medical claim.

Outpatient Institution Services – Line Item 2d1 – Optometrist and Line Item 2d2 - Physical Therapist: Invoices for services rendered under Line Item 2d1 Optometrist and Line Item 2d Physical Therapist, shall be a paper invoice detailing the date(s) sessions were provided, the number of sessions provided, the unit pricing applied, and the extended total amount due. The BOP will not use the services of a third-party medical claims adjudicator for verification of these services.

Telehealth Services – Line Item 2c1 Tele-triage and Line Item 2c2 Telehealth Specialties – All others: Invoices for services rendered under Line Item 2c1 - tele-triage and 2c2 - telehealth specialties – All others, shall be a paper invoice detailing the date(s) of service provided and the per consultation price.

Provider Information

Submission of Provider Data to the BOP's Medical Claims Adjudicator: Within 10 calendar days after notification that a third-party medical claims adjudication service will be utilized by the institution, the contractor shall provide the BOP's medical claims adjudicator with a complete list of provider information, which will enable the medical claims adjudicator to accurately identify the correct payable amount for any provider performing services under the Contract. Specific informational requirements are provided in **Attachment 8-A: List of Provider Information Requirements**. Provider information supplied to the BOP's medical claims adjudicator should be appropriately marked to identify the data as proprietary information so that it may be adequately protected by the BOP and its contracted medical claims adjudicator. Provider information shall be submitted directly to the BOP's medical claims adjudicator. As individual providers are added to the contractor's network, the contractor shall provide the information listed on the List of Provider Information Requirements to the medical claims adjudicator no less than three business days prior to filing claims electronically for services rendered by such new providers.

National Provider Identifier (NPI) Numbers: The contractor shall utilize only providers who have a current NPI number.

Technical Data for Submission of Medical Claims: Prior to the submission of an invoice to the institution, the contractor shall electronically transmit the information found on each individual invoiced medical claim via ANSI 837 format only, to the BOP's medical claims adjudicator. Any claims submitted to the medical claims adjudicator's claims clearinghouse with missing or invalid provider information will be automatically rejected in a 277CA Claims Acknowledgement message noting the missing or invalid provider information received. After the contractor's electronic transmission to the BOP's medical claims adjudicator, the contractor shall promptly submit a paper copy of the invoice to the institution. The contractor will also post the ANSI 837 file in an FTP site set up and maintained by the BOP's medical claims adjudicator. Address information for the submission of a paper claim to the BOP's medical claims adjudicator is provided in **Attachment 8-B: Information Requirements for Medical Claims**, along with other pertinent details.

Procedures for Filing Corrected Medical Claims

A corrected claim is a replacement of a previously submitted claim with claim line level denials or issues. Previously submitted claims that were completely rejected or denied should be sent as a new claim rather than a corrected claim.

Facility Services: If it becomes necessary to file a corrected medical claim for facility services, the contractor shall electronically transmit the information found on each individual corrected medical claim via ANSI 837i format only, to the BOP's medical claims adjudicator. Institutional Provider corrected claims should include a value of '7' (Replacement of Prior Claim) in Loop 2300, Segment CLM05-3.

Physician/Professional Services: If it becomes necessary to file a corrected medical claim for professional services, the contractor shall electronically transmit the information found on each individual corrected medical claim via ANSI 837p format only, to the BOP's medical claims adjudicator. Professional Service Provider corrected claims should include a value of '7' (Replacement of Prior Claim) in Loop 2300, Segment CLM05-3.

After the contractor's submission to the BOP's medical claims adjudicator, the contractor shall promptly submit a paper copy of the invoice or credit memo, as applicable, to the institution. Invoices for corrected medical claims shall be clearly marked as such and shall be separate from routine invoices. Invoices or credit memos for corrected medical claims shall detail information pertaining to the original medical claim submission (including

any amount(s) previously paid and the associated invoice numbers) and shall bill only for the corrected medical claim submission or reflect the credit amount due for the corrected medical claim submission.

Payment by the Institution: The institution will pay all invoices directly to the contractor. If the invoiced amount of a medical claim exceeds the adjudicated amount of that medical claim, the institution will take an administrative deduction from the invoice. The institution will provide written notification to the contractor when an administrative deduction is taken from an invoice payment.

If the contractor is in disagreement with the paid amount of a medical claim, the contractor will provide written notification to the institution of the disagreement along with the reasons why the contractor believes the medical claim was paid incorrectly. The institution will interface between the contractor and the medical claims adjudicator to bring resolution to any disagreements. If it is determined that a medical claim was paid incorrectly by the institution, interest on the underpayment will be paid when required by the Prompt Payment Act.

Timeliness of Medical Claims

Claims shall be submitted/invoiced within 90 calendar days after an Inmate's discharge or outpatient encounter or other service provided under this contract. Medical claims which are submitted/invoiced beyond the 90-day requirement shall constitute a performance deficiency under this output and shall be documented in the contractor's Performance Assessment Report in the Contractor Performance Assessment Reporting System (CPARS). Medical claims which are submitted/invoiced within the acceptable time but are found to contain errors or require further justification, will be rejected and shall be resubmitted/re-invoiced by the contractor within 30 calendar days from the date of rejection. Upon resubmission, invoices for corrected medical claims shall bear the new date of submission.

No later than the 10th of each month, the contractor shall initiate the billing review process by examining its records from the preceding months, including those of all subcontracted providers, to identify an estimated amount of expenditures for services rendered. Using the information gathered through this review, the contractor shall prepare and submit a written monthly estimate of Fiscal Year Obligations. The monthly estimate shall itemize projected amounts by fiscal year and by month, and shall include, at a minimum:

1. Dates of Service
2. Provider
3. Inmate Name
4. Register Number
5. Estimated Amount
6. Billed Amount

Each date of service shall be recorded on its own line. If an inmate has multiple encounters, each encounter shall be listed separately. Each monthly estimate shall address a single month only and shall not be combined with other months. Monthly estimates from prior periods shall be updated as additional services are rendered.

The contractor shall provide the written estimate to the institution no later than the 15th of each month. As invoices are paid, the contractor shall promptly remove them from subsequent estimates. The contractor shall use its best efforts to ensure all estimates submitted to the Government are accurate.

To ensure adequate funds are reserved before the fiscal year ends, the contractor shall provide early estimates for the final two months of the year. Specifically, the contractor shall submit an estimate of services anticipated

for August no later than July 15th, and an estimate of services anticipated for September no later than August 15th.

Output #4: Manage medical record information in a manner which promotes continuity of care while observing restrictions on the release of information.

Upon request, authorized BOP staff shall have access to and obtain copies of all Inmate medical records to include evaluation and treatment reports prepared and maintained by the contract facility and/or contract providers. Inmate medical records will be subject to review by the institution for validation of payment and verification of services rendered. Release of information shall only be made in accordance with community standards, Joint Commission regulations, and the Privacy Act of 1974. Any request(s) for copies of an Inmate's medical records by the Inmate or a third party shall be directed to the COR for processing.

Notwithstanding the above restrictions on the release of information, medical record information shall be provided to the institution to enhance Inmate recovery as well as continuity of care. For inpatient admissions, a faxed report documenting treatment plans will be submitted to the institution Medical Records Department no later than 8 am each day. This form with the requested information will be provided to the institution by the contractor. At the completion of treatment, the contractor shall provide the institution with documented discharge instructions, as provided by the attending physician.

Copies of all lab, x-ray, EKG, progress notes and emergency room working notes shall also accompany the patient or be faxed immediately to the COR. A written report by the attending physician which documents the circumstances of the inpatient treatment, outpatient procedure, or other consultation shall be provided to the COR within ten business days of the inpatient discharge, outpatient procedure, or other consultation. All lab and consultations pending at time of discharge shall be faxed to the COR upon receipt but not later than ten calendar days past discharge.

Output #5: Maintain open avenues of communication, facilitating the exchange of information between the contract physician, contract facility, and the Government regarding the contract services.

The contractor shall provide a Point of Contact (POC) who shall be responsible for facilitating the contractor's delivery of health services under this contract. The POC shall have sufficient clinical knowledge to enable preliminary technical consultation, with referral to a specialist if necessary. The contractor shall designate this individual in writing to the CO prior to the start date of the contract. Alternate POC's may be designated; however, the contractor must identify those times when an alternate shall be the primary POC (i.e., after-hours and weekend referrals).

There shall be an open line of communication between the contractor, its representatives, and the institution to ensure that only those services ordered by the institution are provided, unless required for intervention in a life-threatening emergency. In the event of a life-threatening emergency, the contractor shall contact the COR within a 24-hour period or the next normal working day. All institution referrals shall be the sole responsibility and decision of the Government. No Inmate may be transferred to another medical facility, with exception of emergency cases, without advanced approval by authorized institution medical staff.

A contract provider may discuss with the Inmate patient only the diagnosis and possible treatment options directly related to the written consultation provided by the institution. The contract provider should not guarantee any future treatment to the Inmate or discuss future appointment dates. All consultant recommendations should be sent to the institution for review by the Primary Care Provider Team (PCPT) and/or Clinical Director (CD). The BOP PCPT and/or CD is under no obligation to follow consultant

recommendations. All patient care information and/or treatment plans will be reviewed by the PCPT/CD and the final disposition will be relayed to the Inmate in accordance with BOP policies and procedures. In the event further care is approved, the contractor will be notified by the institution. The contractor shall not perform any treatment/procedures unrelated to the reason for consultation without receiving prior authorization from the institution.

The institution is requiring an Onsite Scheduler to assist in meeting this output. The contractor shall bear all costs associated with the Onsite Scheduler except for: offices located at the institution, phone line and computer. The contractor shall supply all other office supplies (paper, toner, pens, etc.) and equipment (fax, calculator, printer, etc.) necessary for the Onsite Scheduler to perform. Any and all equipment supplied by the contractor shall have prior written approval by the COR. The Onsite Scheduler shall meet and maintain any and all security clearances as required during the life of contract.

The offeror's technical proposal shall discuss in detail, duties and work hours the Onsite Scheduler will perform to assist in achieving Output #5.

IV. Enhancements to the Basic Contract Requirements

Offerors are encouraged to propose enhancements to the basic contract requirements which will facilitate the institution's ability to conform to the BOP's stated mission. Due to security concerns inherent in transporting an Inmate into the community for medical care, it is the institution's preference to treat Inmates within the confines of a secure perimeter whenever possible. Offerings which assist the institution in mitigating security concerns are considered beneficial to the Government and will be evaluated for merit. Enhancements are not additional line items. Pricing for offered enhancements must be absorbed in the line item structure established within Section 2. Offerings of enhancements that are separately priced line items will not be considered or accepted. The Government reserves the right to reject any offered enhancements that are determined not to be in the best interest of the Government.

The offeror's technical proposal shall discuss in detail any such enhancements proposed, including relevant terms and a detailed discussion of the merits of offered enhancements.

V. Prison Rape Elimination Act (PREA)

Institution Health Services staff are responsible for assessment, examination, documentation, and treatment of Inmate injuries arising from incidents of sexual abuse, including testing when appropriate for pregnancy, HIV, and other sexually transmissible infections. Where indicated, medical staff, trained in the collection of sexual assault evidence (e.g., "rape kit") should conduct an examination for physical evidence that may be used later in formal investigations, or refer the Inmate to trained healthcare professionals from the local community or at the local community facility equipped (in accordance with local laws) to evaluate and treat sexual assault victims. Should there be a need for the institution to refer the Inmate out into the community to a trained healthcare professional, the offeror's technical proposal shall discuss in detail the protocol (including but not limited to, the facilities who offer these services, examiners' certifications, and local laws/requirements) to help meet this requirement.

Attachment 3
Computation of Basic MS-DRG Payments (i.e., Operating Federal Rate)
CBSA Code 42 - South Carolina

Calculation of the Operating Federal Rate:

Step 1: Select the applicable average standardized amount for the full update

Step 2: Multiply the labor-related portion of the standardized amount by the applicable wage index for the geographic area

Step 3: For hospitals in Alaska and Hawaii, multiply the nonlabor-related portion of the standardized amount by the applicable cost-of-living adjustment factor

Step 4: Add the amount from Step 2 and the nonlabor-related portion of the standardized amount (adjusted, if applicable, under Step 3)

Step 5: Multiply the final amount from Step 4 by the relative weight corresponding to the applicable MS-DRG

Index Figures: Obtained from the Centers for Medicare and Medicaid Services for discharges on/after **October 1, 2025**

Step 1

Enter CBSA Code in Cell B29 42 .

Table 3, Wage Index Table by CBSA:	0.8506
Area Name:	SOUTH CAROLINA

Table 1A or 1B (Full Update) National Adjusted Operating Standardized Amount:

Labor-related:	$4,186.62
Non-labor-related:	$2,565.99

Table 5, MS-DRG Relative Weight (MS-DRG 76, Viral Meningitis w/o CC/MCC): 0.8252

Step 2
Labor-related x Wage Index $ 3,561.14

Step 3
Only applicable for HI & AK

Step 4
Total of Step 2 + Non-labor related $ 6,127.13

Step 5
Total of Step 4 x MS-DRG Relative Weight **$ 5,056.11**

Payment for MS-DRG 076 under the contract would be **$ 5,056.11** plus or minus any premium or discount established as the contract rate.

CARE LEVEL CLASSIFICATION FOR MEDICAL CONDITIONS OR DISABILITIES

Federal Bureau of Prisons

Clinical Guidance

October 2025

Federal Bureau of Prisons (BOP) Clinical Guidance is made available to the public for informational purposes only. All clinical recommendations, policies, and practices contained herein are grounded in the best available scientific evidence, formulated through transparent, multidisciplinary review processes free from political or non-scientific influence, and aligned with peer-reviewed research and nationally recognized clinical and public health guidelines. The BOP does not warrant this guidance for any other purpose and assumes no responsibility for any injury or damage resulting from the reliance thereof. Proper medical practice necessitates that all cases are evaluated on an individual basis and that treatment decisions are patient specific. Consult the BOP Health Management Resources Web page to determine the date of the most recent update to this document: http://www.bop.gov/resources/health_care_mngmt.jsp.

WHAT'S NEW IN THIS DOCUMENT

This guidance is an update to the May 2019 version. The following major changes were made in this guidance:

- *Initial Designations: After arrival at the designated facility, the provisional care level should be reviewed at the History & Physical or Chronic Care Visit and a nonprovisional care level assigned by the BOP clinician at that time.*
- *Refusal of Care or Non-Compliance* section was updated.
- *Redesignations for Oncology Services: Upon diagnosis of prostate cancer and based on PSA and prostate biopsy results, a treatment plan from a urologist is required to submit a Redesignation Referral Request. Surgery should be performed locally prior to transfer for radiation, chemotherapy, or other adjuvant treatment. Patients for whom active surveillance is appropriate do not need to be transferred and may be monitored at their current institution.*
- Updates made to *Care Levels 1-4 General Descriptions* to include:
  - Removal of "less than 70 years of age" to Care Level 1 description.
  - Addition of the following to Care Level 1 description: *Patients may need multiple medications to control their **CHRONIC** medical conditions or experience **SELF-LIMITED** conditions, but do not require **INTENSIVE CLINICAL INTERVENTIONS** for more than 3-6 months.*
  - Addition of the following to Care Level 2 description:
    - Care Level 2 patients may require increased frequency of evaluations with primary care or specialty clinical consultants or **INTENSIVE CLINICAL INTERVENTIONS** for 3-6 months in order to stabilize their ***CHRONIC*** medical conditions or achieve **OPTIMAL MANAGEMENT**.
    - Patients with stable conditions managed with an implanted device, such as a pacemaker, AICD, or VP shunt may be managed at a Care Level 2 facility.
  - Addition of the following to Care Level 3 description: *Care Level 3 patients may require more than monthly encounters with primary care or specialty clinical consultants after stabilization in order to maintain their chronic conditions.*
- *Appendix 1. Medical Conditions Defaulting to Care Level 3 or 4* was replaced with *Appendix 1. Common Medical Conditions and Corresponding Care Level* and significant changes made throughout.
- *Appendix 3. Instrumental Activities of Daily Living (IADLS)* and *Appendix 4. Physical Self-Maintenance Scale (PSMS)* were added.

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1. PURPOSE

This Federal Bureau of Prisons (BOP) Clinical Guidance for *Care Level Classification for Medical Conditions or Disabilities* provides recommendations for classifying patient's medical conditions so that the patients can be assigned to the BOP institutions that can best manage their health care needs. This document is an update to the May 2019 guidance.

2. GOAL OF THE CARE LEVEL CLASSIFICATION SYSTEM

Prisons are not necessarily built with access to community medical resources in mind. Many federal prisons are in remote rural locations that have limited numbers of specialists and only small community hospitals. The goal of this classification system is to match patient health care needs (particularly in terms of intensity of care issues, access to community medical resources, and functional requirements) with institutions that can meet those needs. The intended result is improved management of these patients' conditions in a manner consistent with community standard of care at a lower overall cost to the agency.

3. DEFINITIONS

ACTIVITIES OF DAILY LIVING (ADLS) OR INSTRUMENTAL ACTIVITIES OF DAILY LIVING (IADLS) are tasks associated with basic self care and independent living and are assessed using the Physical Self-Maintenance and Instrumental Activities of Daily Living tools.

→ See Appendix 3. Instrumental Activities of Daily Living and Appendix 4. Physical Self-Maintenance Scale

CHRONIC CONDITIONS can be reasonably expected to require monitoring or treatment for greater than 12 months. Examples include atrial fibrillation, COPD, diabetes, etc. Certain conditions can also be considered chronic if they require **INTENSIVE CLINICAL INTERVENTIONS** that last beyond a defined limited duration.

→ See Table 1. Time Frames for Intensive Clinical Interventions to be Defined as Chronic below.

FUNCTIONAL STATUS is assessed using ADL/IADL scales and the Physical Self-Maintenance Scale to characterize patients' abilities into three functional groups:

- Independent, no assistance is required
- Assistance from a patient companion is required (the need for a wheelchair or assistance in pushing a wheelchair are not care level criteria and are not indications for a medical transfer)
- Assistance from a health care staff member is required (see **NURSING INTERVENTIONS** below)

INTENSIVE CLINICAL INTERVENTIONS are used to treat, stabilize or monitor a condition after a clinical event, e.g., short-term anticoagulation after a deep vein thrombosis, IV antibiotics for osteomyelitis, or narcotic analgesics after a serious injury. Intensive Clinical Interventions may require an increased frequency of monitoring and/or treatment for a duration of 3–6 months, depending on the type of intervention. Limited periods of intensive clinical interventions are not representative of the patient's normal baseline level of need, which may be much less frequent. Only the patient's baseline needs for **USUAL CLINICAL INTERVENTIONS** are to be used to determine a care level assignment, unless the duration of the intensive intervention becomes chronic.

- **INTENSIVE CLINICAL INTERVENTIONS** beyond a limited duration for some conditions will be considered chronic or indefinite and may warrant an increase in the patient's care level. See Table 1 for a list of time frames for common intensive clinical interventions to be defined as chronic.

- **INTENSIVE CLINICAL INTERVENTIONS** can be used for the purpose of achieving improved clinical indicators of disease management, such as blood pressures, hemoglobin A1C (HbA1C), HIV viral load, peak flows, etc.
- **INTENSIVE CLINICAL INTERVENTIONS** can also include contacts with physicians, APPs, pharmacists, nurses, physical and occupational therapists, and specialists; it can include lab tests, x-rays, wound care, dressing changes, and similar encounters, which may occur as often as daily. Intensive clinical intervention does *not* include pill lines.

TABLE 1. TIME FRAMES FOR INTENSIVE CLINICAL INTERVENTIONS TO BE DEFINED AS CHRONIC

INTERVENTION	TIMEFRAME
IV antibiotics (outpatient)	More than 3 months
Wound care	More than 8 weeks when healing goals are not met, despite optimized basic wound care and consultation with a specialist
Nursing Interventions	More than 3 months for a permanent condition that has reached maximal function
Lab or x-ray monitoring	Tests more frequent than weekly for more than 3 months
Provider contacts (physician, APP)	Weekly to monthly for more than 6 months for the same condition
Specialist consults	At least monthly for more than 6 months in order to maintain outpatient status (i.e., prevent hospitalization)
Supervised PT/OT	More than 3 months

NURSING INTERVENTIONS are a level of care or assistance with ADLs that cannot, by BOP policy, be provided by patient companions. **NURSING INTERVENTIONS** also include tasks that may be performed by other types of staff such as wound care, IV fluid and medication administration, and certain physical or occupational therapy modalities.

OPTIMAL MANAGEMENT is when the health care interventions provided are consistent with BOP clinical guidance, published clinical guidelines, or generally accepted standards of practice, with the goal of achieving desired clinical outcome measures (e.g., target blood pressure, HbA1C levels, or CD4 counts) through a combination of efforts: appropriate medications, clinical monitoring and interventions at intervals necessary to achieve the desired outcomes, and patient participation in and compliance with the treatment plan.

SAFETY/VULNERABILITY are factors considered when determining a care level assignment. Some patients are particularly vulnerable to injury, assault, or victimization due to a physical or mental health condition. Examples may include patients who are blind and deaf, or who have a history of a severe head injury and wander into other cells or are continuously disoriented, etc. This factor should be considered in determining a care level assignment if it is permanent, and if **NURSING INTERVENTIONS** (see above) are required to adequately manage the issues of concern. For example, a blind patient who functions well in a general population institution with the assistance of a patient companion would not score as a Care Level 3 or 4.

SELF-LIMITED conditions can reasonably be expected to resolve within 6 months, with or without medical or surgical treatment. Examples include most infections, fractures, joint sprains, etc. **SELF-LIMITED** also applies to conditions such as hernias, meniscus tears of the knee, and cholelithiasis, where local surgical intervention would reasonably resolve the condition. (Compare to **CHRONIC** above.)

USUAL CLINICAL INTERVENTIONS include chronic care clinic encounters or follow-ups with a physician or advanced practice provider (APP) that are required to maintain the patient in outpatient status, once the patient's major conditions are stable, **OPTIMAL MANAGEMENT** has been achieved, and a long-range treatment plan has been established. The frequency of Usual Clinical Interventions is one primary criterion for determining care level assignment. (Compare to **INTENSIVE CLINICAL INTERVENTIONS** above.)

4. CARE LEVELS

There are four levels in the BOP medical care level classification system. Each patient in custody and each institution are assigned a care level.

- **PATIENT MEDICAL CARE LEVELS** are determined by their medical needs and are based primarily on the chronicity, complexity, intensity, and frequency of interventions and services that are required, as well as a patient's functional capability.
- **INSTITUTION CARE LEVELS** are based primarily on the clinical capabilities and resources of the institution and the surrounding community, as well as specific medical missions, e.g. dialysis, oncology, etc.

DESIGNATION OF INMATE CARE LEVELS

INITIAL DESIGNATIONS

- **CARE LEVELS 1 AND 2:** A provisional care level, identified by "SCRN" in SENTRY, is assigned by the Designation and Sentence Computation Center (DSCC) for newly-sentenced patients meeting Care Level 1 or 2 criteria, based primarily on information contained in the presentence investigation report (PSI).
- **CARE LEVELS 3 AND 4:** The Office of Medical Designations and Transportation (OMDT) performs the provisional "SCRN" care level classification and designation of newly-sentenced patients who meet Care Level 3 or 4 criteria.

After arrival at the designated facility, the provisional care level should be reviewed at the History & Physical or Chronic Care Visit and a non-provisional care level assigned by the BOP clinician at that time.

REDESIGNATIONS

When the health care needs of a BOP patient change to **CARE LEVEL 3 OR 4**, a *Redesignation Referral Request (770)* is submitted in the electronic health record for consideration of transfer.

When the health care needs of a BOP patient at a Care Level 3 or 4 institution change to a **CARE LEVEL 1 OR 2**, a *Treatment Complete Referral Request* (413) is submitted in the electronic health record for consideration of transfer.

Ordinarily, Care Level 3 patients are not redesignated or transferred from one BOP facility to another within 12–18 months of their Projected Release Date (PRD)—taking into consideration potential Residential Reentry Center (RRC) transfer dates—unless the needed services are not available or non-medical issues require the patient to be transferred from their current location. These cases will be reviewed individually and determined on a case-by-case basis.

Redesignations for Oncology Services: A tissue diagnosis and treatment plan are needed, and any urgent necessary surgery locally accomplished, prior to redesignating BOP patients for adjuvant oncology services like chemotherapy, radiation and immunotherapy. There are a few notable exceptions:

- The diagnosis of hepatocellular carcinoma may be confirmed by specialized CT or MRI imaging without the need for biopsy and tissue diagnosis.
- The diagnosis and treatment of sarcoma are often best accomplished at a sarcoma treatment center and may be deferred until transfer if the diagnosis of sarcoma is highly likely based on other available diagnostic tests and specialist evaluations.

Upon diagnosis of prostate cancer, and based on PSA and prostate biopsy results, a treatment plan from a urologist is required to submit a *Redesignation Referral Request*. Any necessary surgery, such as prostatectomy, should be performed locally prior to transfer for radiation, chemotherapy, or other adjuvant treatment. Patients for whom active surveillance is appropriate do not need to be transferred and may be monitored at their current institution.

REFUSAL OF CARE OR NON-COMPLIANCE

Refusal of care, or non-compliance, would not normally change a patient's care level as these levels are usually determined by the underlying medical condition itself. A patient's refusal of treatment solely for the purpose of reducing their care level will not result in a reduction of their care level so long as the underlying condition requiring that treatment persists. An exception may be made only on review by the Regional Medical Director, in conjunction with the Chief of Health Programs, who may determine that a patient who is a Care Level 3 or 4 can be redesignated to a lower care level institution that can monitor the patient throughout the period of refusal or non-compliance.

Care Levels 1-4: General Description

CARE LEVEL 1

- Care Level 1 patients are generally healthy.
- They may have chronic medical conditions that can be easily managed by clinician evaluations every 6–12 months (patients may initially need more frequent contacts in the short-term, up to 3 months, for stabilization of chronic conditions or treatment initiations such as Medications for Opiate Use Disorder (MOUD).
- Patients may need multiple medications to control their **CHRONIC** medical conditions or experience **SELF-LIMITED** conditions, but do not require **INTENSIVE CLINICAL INTERVENTIONS** for more than 3-6 months.

➔ ***Example conditions:*** *Mild asthma, well controlled diabetes, stable HIV patients, well-controlled hyperlipidemia or hypertension, etc.*

CARE LEVEL 2

- Care Level 2 patients are stable outpatients who require primary care or specialist clinician evaluations monthly to every 6 months.
- Their medical conditions can be managed through routine, regularly scheduled appointments with primary or specialist clinicians for monitoring.

- Enhanced medical resources, such as consultation or evaluation by medical specialists, may be required.
- Care Level 2 patients may require increased frequency of evaluations with primary care or specialty clinical consultants or **INTENSIVE CLINICAL INTERVENTIONS** for 3-6 months in order to stabilize their **CHRONIC** medical conditions or achieve **OPTIMAL MANAGEMENT**.
- Patients with stable conditions managed with an implanted device, such as a pacemaker, AICD, or VP shunt may be managed at a Care Level 2 facility.

➔ ***Example conditions:*** *Arrythmia with pacemaker placement, non-intensive insulin initiation for diabetics, prostate cancer treated with prostatectomy alone, heart failure managed with medications, epilepsy, or emphysema.*

CARE LEVEL 3

- Care Level 3 patients may require more than monthly encounters with primary care or specialty clinical consultants after stabilization in order to maintain their chronic conditions.
- Care Level 3 patients are outpatients who have complex and chronic medical conditions who require frequent clinical contacts to maintain control or stability of their condition, or to prevent hospitalization or complications.
- They may require assistance with some activities of daily living (ADLs) that can be accomplished by patient companions.
- Stabilization of medical conditions may require periodic hospitalizations.

➔ ***Example conditions:*** *Paraplegia with chronic wounds requiring wound care, chronic kidney disease preparing for dialysis, diabetics with intensive insulin regimens, cancer in partial remission, advanced HIV disease, severe (NYHA Class III) heart failure, and end-stage liver disease.*

CARE LEVEL 4

- Care Level 4 patients require services available only at a BOP Medical Referral Center (MRC), which provides significantly enhanced medical services and limited inpatient care.
- Functioning is so severely impaired as to require 24-hour skilled nursing care or nursing assistance.

➔ ***Example conditions:*** *Cancer on active treatment, dialysis, quadriplegia, inability to perform ADLs due to stroke or dementia, major post-operative in-person physical therapy requirements, and high-risk pregnancy.*

USE OF THE APPENDICES IN DETERMINING A PATIENT'S CARE LEVEL

The **APPENDICES** are useful guides for determining a patient's care level.

- *Appendix 1* lists specific conditions and their assigned care level classification. Any condition not specifically listed in this appendix can be classified according to the Appendix 2 Care Level Algorithm.
- *Appendix 2* provides an algorithm for determining care levels that are not covered by the first appendix.
- *Appendix 3* provides **ADL/IADL** and **PHYSICAL SELF-MAINTENANCE SCALES**

APPENDIX 1. COMMON MEDICAL CONDITIONS AND CORRESPONDING CARE LEVEL

CONDITION/DIAGNOSIS	CRITERIA/CARE LEVEL
AUTOIMMUNE/CONNECTIVE TISSUE/RHEUMATOLOGIC CONDITIONS	
Autoimmune/Chronic Connective Tissue/ Rheumatologic Diseases	**CARE LEVEL 3** • IV immunomodulator infusion, e.g., infliximab, vedolizumab, etc., approved by non-formulary request (NFR) and for which there is no acceptable subcutaneous injection, e.g., adalimumab, anakinra, certolizumab, etanercept
CARDIOVASCULAR CONDITIONS	
Heart Failure	**CARE LEVEL 1 – No symptoms and no limitations in physical activity.** • No symptoms of heart failure **CARE LEVEL 2 – Mild symptoms and slight limitations during activity.** • NYHA Class I or II **CARE LEVEL 3 – Significant limitations in activity due to symptoms. Only comfortable at rest.** • NYHA Class III **CARE LEVEL 4 – Severe limitations. Symptoms even while at rest.** • NYHA Class IV
Hypertension	**CARE LEVEL 2** • Blood pressure control requires three or more medications ***OR*** • Presence of persistent hypertension related complication
Pulmonary Arterial Hypertension	**CARE LEVEL 3** • Requires oral medications for PAH (WHO functional class II and III or low/intermediate risk) **CARE LEVEL 4** • Require parenteral prostanoid-containing regimens (WHO functional class IV or high risk)

CONDITION/DIAGNOSIS	CRITERIA/CARE LEVEL
DIABETES MELLITUS (DM)	
DM Type 2	**CARE LEVEL 1** • Well-controlled (HbA1C no more than 7) without insulin and no serious end organ complications* **CARE LEVEL 2** • Insulin therapy is required no more than 2 times per day to achieve glycemic control. • HbA1C >7 for at least 12 months despite compliance with optimal therapy • No more than 2 serious end-organ complications*
	CARE LEVEL 3 • Three times per day insulin therapy required to achieve glycemic control OR • More than two serious end-organ complications* OR • Poorly controlled (HbA1C greater than 9%) for at least 12 months, despite compliance with optimal therapy OR • Insulin pump
DM Type 1	**CARE LEVEL 3**
***** Examples of serious end-organ complications: **Diabetic nephropathy** – Progressive kidney damage leading to chronic kidney disease **Diabetic retinopathy** – Damage to the blood vessels in the retina, potentially resulting in vision loss or blindness. **Diabetic neuropathy** – Nerve damage which can increase the risk of infections and amputations	
ENDOCRINOLOGIC CONDITIONS	
Addison's Disease	**CARE LEVEL 3**
Panhypopituitarism	**CARE LEVEL 3**
GASTROINTESTINAL CONDITIONS	
Inflammatory Bowel Disease	**CARE LEVEL 1** • Asymptomatic on treatment **CARE LEVEL 2** • On treatment with infrequent flares of symptoms (less than monthly) **CARE LEVEL 3** • Persistent or poorly controlled symptoms for greater than 3–6 months, despite optimal treatment with chronic steroid and/or immunomodulator therapy ***OR*** • IV immunomodulator infusion, e.g., infliximab, vedolizumab, etc., approved by non-formulary request and for which there is no acceptable subcutaneous injection, e.g., adalimumab, anakinra, certolizumab, etc.

CONDITION/DIAGNOSIS	CRITERIA/CARE LEVEL
HEMATOLOGIC CONDITIONS	
Sickle Cell Anemia	**CARE LEVEL 3** • Sickle Cell Crisis more often than every 2 years despite optimal management ***OR*** • Weekly clinical interventions needed to maintain outpatient status **CARE LEVEL 4** • Needs daily nursing care
Hemophilia	**CARE LEVEL 3** • Antihemophilic therapy needed to maintain outpatient status
Miscellaneous Hematologic Disorders	Use *Appendix 2, Medical Classification Algorithm*.
HEPATIC DISEASE	
Cirrhosis *(end-stage liver disease)*	**CARE LEVEL 3** • Weekly clinical interventions needed to maintain outpatient status ***OR*** • Decompensated cirrhosis, as evidenced by any one of the following: moderate ascites, encephalopathy, INR ≥ 1.7, platelet count < 50,000, or a history of bleeding esophageal varices. These cases will be transferred preferentially to available MRC Care Level 3 sites as security levels allow. **CARE LEVEL 4** • Needs daily nursing care
INFECTIOUS DISEASE	
HIV	**CARE LEVEL 1** On antiretroviral therapy (ART): • Asymptomatic ***AND*** • Absolute CD4 cell count > 500 cells/uL ***AND*** • Undetectable viral load **CARE LEVEL 2** • Absolute CD4 cell count between 200 and 500 cells/uL following at least 6 months of appropriate ART, when compliant with treatment **CARE LEVEL 3** • Absolute CD4 cell count > 50 and < 200 cells/uL following at least 6 months of appropriate ART therapy, when compliant with treatment ***OR*** • Failed therapy despite adequate treatment with 2 different ART regimens, confirmed with resistance patterns on genotype testing **CARE LEVEL 4** • CD4 count < 50 cells/uL, following at least 6 months of appropriate ART therapy, when compliant with treatment

CONDITION/DIAGNOSIS	CRITERIA/CARE LEVEL
MALIGNANCIES	
• A tissue diagnosis and a treatment plan are required prior to redesignation/transfer of cancer cases. ► Examples of malignancies that may NOT require a tissue diagnosis include hepatocellular carcinoma, soft tissue sarcoma with characteristic radiographic features, or unless tissue diagnosis not recommended by Oncology (i.e., brain malignancy). • Necessary surgery is usually performed locally prior to redesignation/transfer of cancer cases. • Prostate cancer can often be treated at the local level unless it is metastatic.	
General Criteria for Malignancies	**CARE LEVEL 1** • Cured and no further monitoring required ***OR*** • In full remission for ≥ 2 years, with low risk of relapse, and monitoring less frequently than every 6 months ***OR*** • Skin cancers that do not require systemic therapy and treatment is available locally **CARE LEVEL 2** • In full remission < 2 years ***OR*** • Requires ongoing, infrequent monitoring every 1–6 months **CARE LEVEL 3** • In partial remission ***OR*** • Requires intensive monitoring, but is not being actively treated with systemic chemotherapy or radiation **CARE LEVEL 4** • Requires treatment with systemic chemotherapy, radiation, or organ transplantation
Chronic Lymphocytic Leukemia (CLL)	**CARE LEVEL 2** • Asymptomatic, early-stage disease, and treatment not indicated. Periodic surveillance (e.g., every 3 months and as clinically indicated) recommended with CBC + diff and clinical exam. **CARE LEVEL 4** • Symptomatic disease (weakness, night sweats, fever, weight loss, painful lymphadenopathy, recurrent infection) ***OR*** • Advanced stage disease (Hgb < 11 gm/dL, or platelet count < 100,000, or WBC > 100,000) ***OR*** • Refractory or relapsed disease ***OR*** • Second lymphoid/hematologic malignancy

CONDITION/DIAGNOSIS	CRITERIA/CARE LEVEL
MALIGNANCIES (CONTINUED)	
Chronic Myelogenous Leukemia (CML)	**CARE LEVEL 3** • CML in chronic phase with complete hematologic and cytogenetic responses and at least a major molecular response after 12–18 months of treatment with a first- or second-line tyrosine kinase inhibitor (TKI) (e.g., imatinib, desatinib, nilotinib) ▸ Complete hematologic response (normal CBC with diff, asymptomatic, and resolution of splenomegaly) ***AND*** ▸ Complete cytogenetic response (no Ph-positive metaphases on bone marrow aspirate and cytogenetics) ***AND*** ▸ Major molecular response (either 0.1% BCR-ABL1 by QPCR or ≥ 3-log decrease from baseline of BCR-ABL1 mRNA from peripheral blood sample) **CARE LEVEL 4** • CML in accelerated or blast phase ***OR*** • CML in chronic phase with an incomplete response after 12–18 months of treatment with a first- or second-line tyrosine kinase inhibitor (TKI) (e.g., imatinib, desatinib, nilotinib), intolerance of TKI treatment, or relapse of chronic phase after an initial response as noted under **CARE LEVEL 3** criteria
Prostate Cancer	**CARE LEVEL 1** • Very low-risk or low-risk prostate cancer for which active surveillance and postponement of treatment is appropriate **CARE LEVEL 2** • Localized prostate cancer cases that have completed appropriate treatment, with a good PSA response and no significant complications at least one month after completion of treatment, and with or without androgen deprivation therapy, e.g., leuprolide *(Treatment complete transfer requests from an MRC to a general population facility must include a surveillance and treatment plan.)* ***OR*** • Stage IV prostate cancer cases at least one month after completion of (and without complications from) any radiation or surgery and whose metastatic disease is asymptomatic or well-controlled on androgen deprivation therapy **CARE LEVEL 4** • Inmates with biopsy-confirmed prostate cancer who require adjuvant treatment with chemotherapy or radiation OR • Stage IV prostate cancer cases (lymph node involvement or disseminated metastases) that have completed primary treatment whose metastatic disease remains symptomatic or is not controlled with androgen deprivation therapy

CONDITION/DIAGNOSIS	CRITERIA/CARE LEVEL
NEUROLOGIC CONDITIONS	
Chronic Non-Progressive Neurological Conditions *(cerebral palsy, history of stroke, intellectual disabilities, paralysis, seizure disorder, etc.)*	Use *Appendix 2. Medical Classification Algorithm*, *Appendix 3. Instrumental Activities of Daily Living*, *and Appendix 4. Physical Self-Maintenance Scales* to determine if patient requires assistance with ADLs/IADLs, such as toileting, bathing, and/or dressing which may be classified as **CARE LEVEL 4**
Progressive Neurological Conditions *(dementia, Huntington's chorea, multiple sclerosis, myasthenia gravis, Parkinson's disease, etc.)*	**CARE LEVEL 3** • Persistent or poorly controlled symptoms for greater than 3–6 months, despite compliance with optimal treatment with chronic steroid and/or immunomodulator therapy ***OR*** • IV immunomodulator infusion, e.g., infliximab, vedolizumab, etc., approved by NFR and for which there is no acceptable subcutaneous injection, e.g., adalimumab, anakinra, certolizumab, etanercept • Requires assistance from an inmate companion to perform allowed ADLs in an outpatient setting and not yet meeting the algorithm criteria for **CARE LEVEL 4** (does not yet require 24-hour skilled nursing care or nursing assistance) **CARE LEVEL 4** • Use *Appendix 2. Medical Classification Algorithm*, *Appendix 3. Instrumental Activities of Daily Living*, *and Appendix 4. Physical Self-Maintenance Scales* to determine if patient requires assistance with ADLs/IADLs, such as toileting, bathing, and/or dressing which may be classified as **CARE LEVEL 4** • Severe Functional limitations due to cognitive or physical impairment that prevent successful management in general population, despite appropriate assistance from an inmate companion in performing allowed ADLs or the use of durable medical equipment OR • Requires daily assistance from health care staff on a health care unit, e.g., memory unit or nursing care unit

CONDITION/DIAGNOSIS	CRITERIA/CARE LEVEL
ORTHOPEDIC CONDITIONS	
Arthroplasty of a Major Joint or Other Orthopedic Surgery	**Uncomplicated anterior total hip replacements, knee arthroscopy, or meniscus repair** may be considered for care level redesignation on a case-by-case basis in consultation with the Regional Physical Therapy Consultant and Regional Medical Director. Decisions will be based in part on the clinical fitness of the patient and local physical therapy resources. **CARE LEVEL 4** • Arthroplasty candidate for a posterior total hip replacement, major knee or shoulder replacement, labral repair or rotator cuff repair, anterior cruciate ligament surgery or other total hip replacement with complications. • BOP criteria for surgery are met, as described in BOP Clinical Practice Guidelines: *Evaluation and Management of Osteoarthritis of the Hip and Knee* and *Management of Anterior Cruciate Ligament Injuries*.
PAIN MANAGEMENT	
Chronic Pain	**CARE LEVEL 1** • Does not require long-term (> 90days) opioid medications while in BOP after adequate BOP evaluation **CARE LEVEL 2** • Requires long-term (> 90 days) opioid medications (other than MOUD therapy) while in BOP after adequate BOP evaluation **CARE LEVEL 3** • Requires weekly clinical interventions on a chronic basis, other than for medication renewal, OR • Has an active implanted device, such as a spinal cord stimulator (does not include TENS)
PREGNANCY	
High-Risk Pregnancy	**CARE LEVEL 4** • Pregnancy-specific conditions: Multiple gestations, pre-eclampsia, 2nd/3rd trimester bleeding OR • Other medical conditions: Pulmonary hypertension, serious heart disease, uncontrolled diabetes, sickle cell disease, cancer, and/or serious mental health issues being treated with medications.

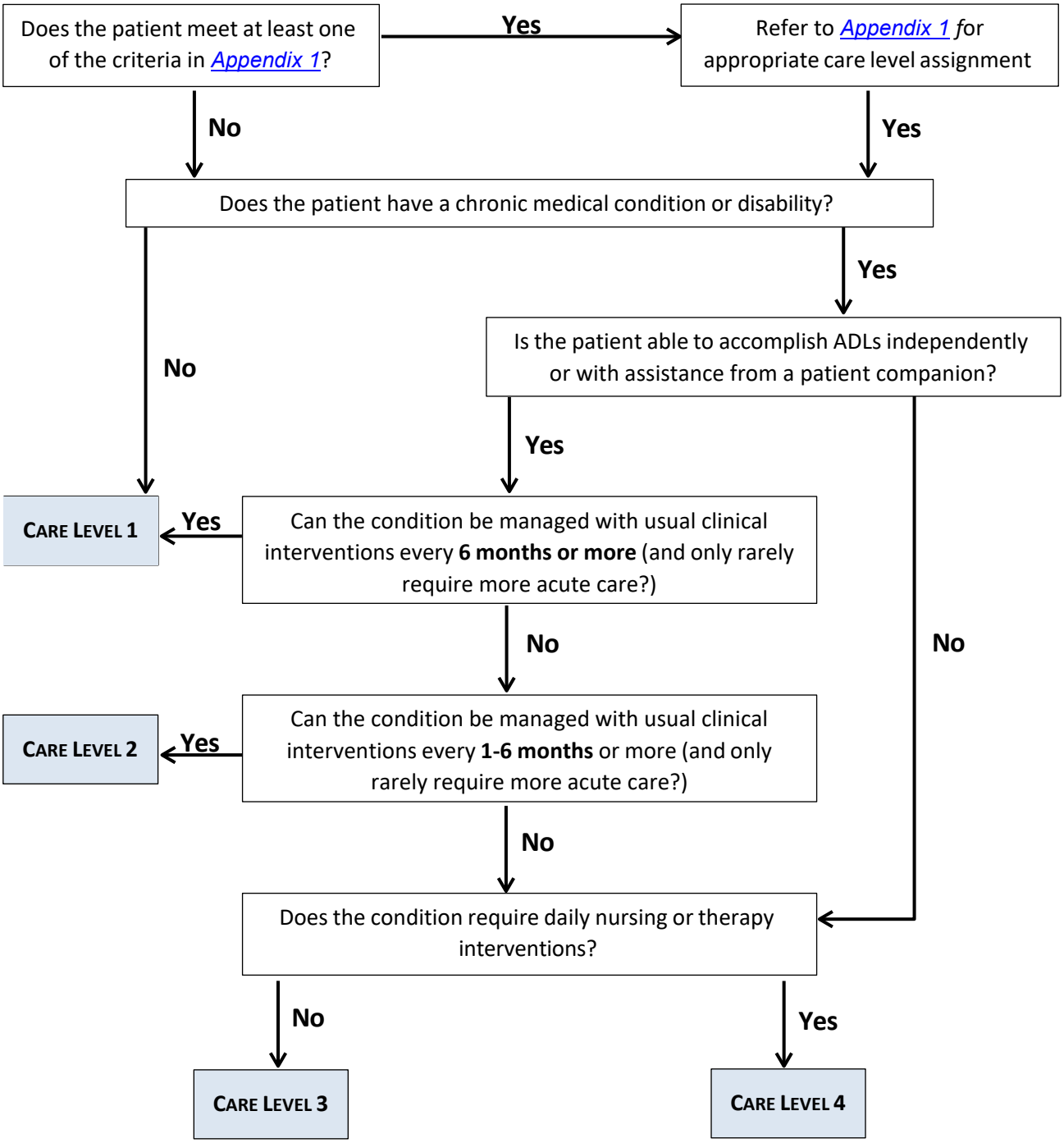
CONDITION/DIAGNOSIS	CRITERIA/CARE LEVEL
RENAL DISEASE	
Chronic Kidney Disease (CKD)	**CARE LEVEL 3** • GFR < 30, but not yet on dialysis, ***AND*** ► Persistent metabolic acidosis requiring medication and frequent monitoring. ► Vitamin D and calcium irregularities requiring medication and frequent monitoring. ► Uncontrolled hypertension despite 3 or more anti-hypertensive medications. *(Decisions to transfer to an MRC population with access to dialysis will be based in part on the likelihood of progression to dialysis)* • Other medical complications considered on a case-by-case basis in consultation with the Regional Medical Director. **CARE LEVEL 4** • Dialysis
RESPIRATORY CONDITIONS	
Asthma	**CARE LEVEL 3** • History of intubation, status asthmaticus, or hospitalization for stabilization in the previous 5 years OR • Requires clinical interventions more frequently than monthly to maintain outpatient status, despite optimized treatment (does not include nebulizer treatments) OR • Severe persistent asthma severity for greater than 3–6 months, despite optimized treatment, e.g., high-dose inhaled corticosteroids plus a second controller and/or chronic systemic steroid therapy **CARE LEVEL 4** • Requires daily nursing care on chronic basis **OR** • Requires 24-hour oxygen supplementation

CONDITION/DIAGNOSIS	CRITERIA/CARE LEVEL
RESPIRATORY CONDITIONS (CONTINUED)	
COPD/Emphysema *GOLD and NICE classification systems categorize disease severity based on spirometry results and symptom assessment using a validated questionnaire, such as the modified Medical Research Council (mMRC) dyspnea scale or the COPD Assessment Test (CAT)*	**CARE LEVEL 3 – High Risk, Fewer Symptoms** • GOLD 3 spirometry classification (Postbronchodilator FEV1 30-49% of predicted) • NICE classification – Severe • Exacerbations per year ≥ 2 • Hospitalization per year ≥ 1 • MMRC score 0 or 1 • CAT score <10 • Nocturnal or intermittent oxygen requirement. **CARE LEVEL 4 – High Risk, More Symptoms** • GOLD 4 spirometry classification (Postbronchodilator FEV1 <30% of predicted) • NICE classification – Very Severe • MMRC score ≥ 2 • CAT score ≥ 10 • Requires 24-hour oxygen supplementation
Cystic Fibrosis	Please consult with Regional Medical Director
Oxygen-Dependence	**CARE LEVEL 3** • Nocturnal or intermittent oxygen requirement. **CARE LEVEL 4** • 24-hour/continuous oxygen requirement.
OTHER *(restrictive lung disease, sarcoid, etc.)*	Use *Appendix 2. Medical Classification Algorithm.*

CONDITION/DIAGNOSIS	CRITERIA/CARE LEVEL
WOUND CARE	
Wounds	**CARE LEVEL 3** [1] • Indications for more advanced wound therapy, e.g., negative pressure wound therapy (wound Vac) or hyperbaric oxygen (HBO)[2] • Other chronic wounds not meeting healing goals despite optimized basic wound care interventions as described in the BOP Clinical Guidance on Wound Prevention and Management available on the Health Services Sallyport page and as recommended by a certified wound care specialist or licensed independent practitioner experienced with wound management, considered on a case-by-case basis.[3] ▸ Diabetic/neuropathic foot ulcers ▸ Vascular ulcers: arterial or venous ▸ Open surgical, atypical, or complex wounds **CARE LEVEL 4** [1] **Any of the following conditions:** • Any current stage 3 or 4 pressure ulcer not responding to optimal therapy after wound care consultation and treatment • Chronic wounds requiring surgical interventions as recommended by an appropriate specialist: ▸ Cases requiring *non-urgent* surgical interventions on weight-bearing surfaces should be submitted for transfer prior to surgery. ▸ Cases requiring *urgent* surgical intervention should have surgery completed locally prior to considering transfer. ▸ Angioplasty/vascular bypass surgery for arterial occlusion should be accomplished locally. • Postoperative management of flaps on weight-bearing surfaces and diabetic foot ulcers when ready for hospital discharge ▸ Require off-loading over the ulcer/surgery site until arrival at the MRC. • Chronic wounds with underlying osteomyelitis ▸ Excluding infected orthopedic hardware or non-wound related osteomyelitis

CONDITION/DIAGNOSIS	CRITERIA/CARE LEVEL
WOUND CARE (CONTINUED)	
NOTES on Wound Care Consultations and Redesignation Requests [1] **All consultations or transfer requests for wound care must be supported by documentation, both in the request and in the medical record**, and must include specific and detailed information about the wound including wound duration, location, type/cause, size measurements (initial, current, and 2 weeks prior), color(s) of wound bed, presence of drainage and slough, involvement of deep tissues (such as fascia, muscle, or bone), presence of infection, relevant diagnostic studies, current and past treatments, specific indications for advanced wound therapies, and a photo of the wound loaded into BEMR. For hospitalized inmates, institution clinical staff should obtain as much of this information as possible (including a current treatment plan) from the hospital. Detailed instructions on how to upload a photo in BEMR and to submit a consult to the BOP National Wound Management Program (NWMP) are available on Sallyport: Health Services Division Homepage - Health Programs – National Wound Management Program. [2] **The role of HBO in the treatment of wounds is not clearly established and must be reviewed and approved prior to initiating treatment,** by the Regional Medical Director for patients at mainline institutions (**CARE LEVELS 1–3**) or by the Chief of Health Programs for patients at **CARE LEVEL 4** sites. Refer to the *BOP Clinical Guidance on Wound Prevention and Management* which can be found on Sallyport (Health Services Division Homepage – Clinical Guidance Documents) for further discussion of advanced wound therapies. [3] **Prior to requesting a medical transfer**, telehealth consultation with the NWMP should be obtained if treatment/healing goals are not met after 4 weeks. Directions to submit a consultation request to the NWMP are	
OTHER CONDITIONS AND INTERVENTIONS	
	CARE LEVEL 3 • Anticoagulation with warfarin for more than 6 – 12 months • Systemic steroids for more than 6 – 12 months • Organ transplant more than 1 year ago, and without complications
	CARE LEVEL 4 • Clinical or nursing interventions required daily or near daily for more than 3 months • Functional limitations due to cognitive or physical impairment that prevent successful management in general population, despite appropriate assistance from an inmate companion in performing ADLs or the use of durable medical equipment • Organ transplant (excluding cornea) candidate or transplant accomplished less than 1 year ago

APPENDIX 2. MEDICAL CLASSIFICATION ALGORITHM



APPENDIX 3. INSTRUMENTAL ACTIVITIES OF DAILY LIVING (IADLS)

This tool is useful for indicating how a person is performing IADL tasks at the present time. For each task area (A–I), circle the score (1 or 0) for the statement that most closely corresponds to the inmate's current functional ability. The scoring should be based on information gathered about the inmate from the inmate him/herself, cellmates, inmate care companions/nursing assistants, staff, and recent records.

Inmate Name: **Reg. No.:**

A. Telephone Use	**Score**
1. Operates telephone on own initiative; looks up and dials numbers, etc.	1
2. Dials a few well-known numbers.	1
3. Unable to use telephone without human assistance.	0
SCORE FOR TASK A (1 OR 0):	

B. Computer Use	**Score**
1. Uses the computer to communicate with staff and family via email.	1
2. Needs assistance to use the computer.	1
3. Unable to use the computer at all.	0
SCORE FOR TASK B (1 OR 0):	

C. Shopping	**Score**
1. Able to complete commissary list and manage commissary independently.	1
2. Needs assistance to complete commissary list and managing commissary.	0
3. Needs to be accompanied to commissary for full assistance.	0
4. Completely unable to shop.	0
SCORE FOR TASK C (1 OR 0):	

D. Food Preparation/Nutrition	**Score**
1. Able to independently plan and prepare snacks/meals outside of food services.	1
2. Needs assistance to plan and prepare snacks/meals outside of food services.	0
3. Does not maintain adequate diet by eating snacks or going to food service.	0
4. Needs complete assistance in obtaining meals.	0
SCORE FOR TASK D (1 OR 0):	

E. Housekeeping	**Score**
1. Maintains cell independently according to BOP Policy.	1
2. Performs light daily tasks such as dishwashing and bed making.	1
3. Performs light daily tasks, but cannot maintain acceptable level of cleanliness.	0
4. Needs help with all housekeeping tasks.	0
5. Does not participate in any housekeeping tasks.	0
SCORE FOR TASK E (1 OR 0):	

F. Laundry	**Score**
1. Does personal laundry completely.	1
2. Launders small items; rinses socks, etc.	1
3. All laundry must be done by others.	0
SCORE FOR TASK F (1 OR 0):	

G. Mode of Transportation If Released	**Score**
1. Able to travel independently on public transportation or drive own car.	1
2. Able to arrange own travel via taxi, but would not otherwise be able to use public transportation.	1
3. Able to travel on public transportation when assisted or accompanied by another.	0
4. Travel would be limited to taxi or automobile with assistance of another.	0
5. Would not travel at all.	0
SCORE FOR TASK G (1 OR 0):	

H. Responsibility for Own Medications	**Score**
1. Is responsible for taking medication in correct dosages at correct times.	1
2. Takes responsibility if medication is prepared in advance in separate dosages.	0
3. Is not capable of managing own medication.	0
SCORE FOR TASK H (1 OR 0):	

I. Ability to Handle Finances	**Score**
1. Manages TRULINCS account independently.	1
2. Needs help managing account.	1
3. Incapable of managing account.	0
SCORE FOR TASK I (1 OR 0):	

SCORING: The patient receives a score of 1 for each task section (A–I) if his or her ability is rated at some minimal level or higher. Add the points circled for tasks A–I. The total score may range from 0–9. The lower the total score, the higher the level of dependence.

TOTAL SCORE FOR SECTIONS A–I:

Completed By *Date*

Adapted for use in the correctional environment from: Lawton MP, Brody EM, *Assessment of Older People: Self-Maintaining and Instrumental Activities of Daily Living. Gerontologist 9 (1969):179-186.*

APPENDIX 4. PHYSICAL SELF-MAINTENANCE SCALE (PSMS)

This tool is useful for indicating specifically how a person is performing at the present time. For each activity (A–F), circle the score (1 or 0) for the statement that most closely corresponds to the inmate's current functional ability. Then, add together the task scores to arrive at the total. The scoring should be based on information gathered about the inmate from the inmate him/herself, cellmates, inmate care companions/nursing assistants, staff, and recent records.

Inmate Name: **Reg. No.:**

A. Toilet	Score
1. Care for self at toilet completely; no incontinence.	1
2. Needs to be reminded, or needs help in cleaning self, or has rare (weekly at most) accidents.	0
3. Soiling or wetting while asleep, more than once a week.	0
4. Soiling or wetting while awake, more than once a week.	0
5. No control of bowels or bladder.	0
SCORE FOR TASK A (1 OR 0):	

B. Feeding	Score
1. Eats without assistance.	1
2. Eats with minor assistance at meal times and/or with special preparation of food, or needs help in cleaning up after meals.	0
3. Feeds self with moderate assistance and is untidy.	0
4. Requires extensive assistance at all meals.	0
5. Does not feed self at all and resists efforts of others to feed him or her.	0
SCORE FOR TASK B (1 OR 0):	

C. Dressing	Score
1. Dresses, undresses, and wears uniform according to BOP Policy.	1
2. Dresses and undresses self, with adaptive equipment.	1
3. Needs moderate assistance in dressing.	0
4. Needs major assistance in dressing, but cooperates with efforts of others to help.	0
5. Completely unable to dress self and resists efforts of others to help.	0
SCORE FOR TASK C (1 OR 0):	

D. Grooming	Score
1. Always neatly dressed, well-groomed, without assistance.	1
2. Needs moderate and regular assistance or supervision with grooming.	0
3. Needs total grooming care, but can remain well-groomed after help from others.	0
SCORE FOR TASK D (1 OR 0):	

E. Physical Ambulation	Score
1. Moves about the unit and institution independently.	1
2. Ambulates only short distances	0
3. Ambulates w/ assistance of (✓ all that apply): ☐ Another person ☐ Railing ☐ Cane ☐ Walker ☐ Wheelchair, transfers without help ☐ Wheelchair, needs help to transfer	0
4. Sits unsupported in chair or wheelchair, but cannot propel self without help.	0
5. Bedridden more than half the time.	0
SCORE FOR TASK E (1 OR 0):	

F. Bathing	Score
1. Bathes self (tub, shower, sponge bath) without human assistance.	1
2. Bathes self with help getting in and out of tub or shower.	0
3. Washes face and hands only, but cannot bathe rest of body.	0
4. Does not wash self, but is cooperative with those who bathe him or her.	0
5. Does not try to wash self and resists efforts to keep him or her clean.	0
SCORE FOR TASK F (1 OR 0):	

SCORING: The inmate receives a score of 1 for each task section (A–F) if his or her ability is rated at some minimal level or higher. Add the points circled for tasks A–F. The total score may range from 0–6. The lower the total score, the higher the level of dependence.

TOTAL SCORE FOR SECTIONS A–F:

Completed By *Date*

Adapted for use in the correctional environment from:
Lawton MP, Brody EM, *Assessment of Older People: Self- Maintaining and Instrumental Activities of Daily Living. Gerontologist 9 (1969):179-186.*

Performance Element: Quality of Goods/Services

Outcome Measure Indicators:

- Degree to which the care provided to the Inmate was considered to be appropriate. Extent to which the Inmates received the services for which they were referred.
- Degree to which services were provided that were not authorized by the Government.
- Extent to which the contractor submitted invoices which were accurate, properly documented, and billed in accordance with the terms of the contract.
- Extent to which the evaluation and treatment was completely documented, accurate, legible, and of the appropriate content.
- Degree to which the discharge instructions provided by the attending physicians were in sufficient detail to allow subsequent care of the patients.
- Degree to which the contractor's assigned Point of Contact was knowledgeable and available for consultation.

Performance Element: Timeliness of Deliveries/Performance

Outcome Measure Indicators:

- Degree to which the medical care was provided in a timely manner.
- If applicable, degree to which the scheduling of appointments was completed in a timely manner, given the urgency of the referrals.
- Extent to which appointments for specialty care were generally available within 14 calendar days from date of referral to the specialty provider.
- Degree to which invoices were received within 90 calendar days after an Inmate's discharge or outpatient encounter.
- When improper invoices were rejected, extent to which the revised invoices were resubmitted within 30 calendar days from the date of rejection.
- Degree to which written reports by the attending physician documenting the circumstances of the inpatient treatment, outpatient procedure, or other consultation were provided to the COR within ten business days of the inpatient discharge, outpatient procedure, or other consultation.
- Degree to which the contractor's assigned Point of Contact provided prompt assistance and coordination in the provision of the contract services.
- Extent to which labs and consultations pending at time of discharge were faxed to the COR no later than ten calendar days past discharge.

Performance Element: Business Relations

Outcome Measure Indicators:

- Extent to which the contractor coordinated and integrated the provision of care while the Inmate was in a community-based setting. Degree to which the attending physician or coordinator of care responded in a timely manner to requests for information from the Health Services Administrator, Clinical Director, or other designated POC regarding the health status of the Inmate.
- Extent to which the contractor cooperated with the Government in the review of invoices, answering questions as needed and providing clarifying information.
- Extent to which the contractor released Inmate medical information in a timely manner, and in a manner consistent with applicable law or regulation. Degree to which the contractor facilitated open avenues of communication between the physician, hospital/facility, and the Government regarding patient care and/or administration issues. Extent to which the contractor was effective in interfacing with BOP Health Services staff. Extent to which the contractor maintained positive relationships with the provider network.

Performance Element: Customer Satisfaction

Outcome Measure Indicators:

- Overall level of satisfaction with the hospital/facility services provided. Overall level of satisfaction with the physician services provided.
- Overall level of satisfaction with the invoicing/billing performed by the contractor.
- Overall level of satisfaction with the contractor's management of medical record information. Overall level of satisfaction with the contractor's communication efforts.

Each offeror shall complete this two-page attachment for each hospital network proposed, without altering the format or the information sought by the form. The completed attachment supersedes any information described in the technical proposal. In the event of any conflicts between the completed attachment and the technical proposal, the information provided in this attachment shall take precedence.

Offeror:
Hospital provider (name, address):
Type of facility (e.g., acute, tertiary, ambulatory surgery):
Accreditation type/date:
Proximity of hospital to Institution (in miles):
Number/type of beds:
Any exclusions on hospital services offered? (if so, describe):
Emergency Room trauma level:
Based on proximity and/or capability, is this hospital the primary Emergency Room provider for Institution inmates, as recognized by the local emergency medical service responder?
Summarize enhancements available at this hospital:
Describe how this hospital network would be utilized within the offeror's overall provider network (e.g., primary provider, secondary provider, etc.):

Physician Specialties in this hospital network	Offered?	# of Physicians	Physician Specialties in this hospital network	Offered?	# of Physicians
1. Anesthesiology			26. Other:		
2. Cardiology/Surgery			27. Other:		
3. Dermatology			28. Other:		
4. Emergency Room			29. Other:		
5. ENT/Surgery			30. Other:		
6. Endocrinology			31. Other:		
7. Family Medicine			32. Other:		
8. Gastroenterology			33. Other:		
9. General Surgery			34. Other:		
10. Gynecology (if female)			35. Other:		
11. Hematology			36. Other:		
12. Infectious Disease			37. Other:		
13. Internal Medicine			38. Other:		
14. Nephrology			39. Other:		
15. Neurology			40. Other:		
16. Obstetrics (if female)			41. Other:		
17. Oncology			42. Other:		
18. Ophthalmology			43. Other:		
19. Optometry			44. Other:		
20. Orthopedics/Surgery			45. Other:		
21. Pathology			46. Other:		
22. Psychiatry			47. Other:		
23. Pulmonology			48. Other:		
24. Radiology			49. Other:		
25. Urology			50. Other:		

Proximity of physician offices to the Institution: Minimum _____ miles Maximum _____ miles

Hospital Services		
1.	21.	41.
2.	22.	42.
3.	23.	43.
4.	24.	44.
5.	25.	45.
6.	26.	46.
7.	27.	47.
8.	28.	48.
9.	29.	49.
10.	30.	50.
11.	31.	51.
12.	32.	52.
13.	33.	53.
14.	34.	54.
15.	35.	55.
16.	36.	56.
17.	37.	57.
18.	38.	58.
19.	39.	59.
20.	40.	60.

Each offeror shall complete this one-page attachment for the Institution-Based Services proposed without altering the format or the information sought by the form. The completed attachment supersedes any information described in the technical proposal. In the event of any conflicts between the completed attachment and the technical proposal, the information provided in this attachment shall take precedence.

Institution-based specialty(s) required by the institution.	**Does your firm offer this specialty in your proposal?**	**If so, what in-network facility(s) does the specialist have privileges at, if applicable?**	**Will the provider also perform services within an inpatient, outpatient, or office setting? If so, indicate which below.**
Optometrist			
Physical Therapist			

Proximity of physician offices to the Institution:
Minimum _____ miles Maximum _____ miles

The offeror shall complete this attachment, without altering the format or the information sought by the form. The completed attachment supersedes any information described in the technical proposal. In the event of any conflicts between the completed attachment and the technical proposal, the information provided in this attachment shall take precedence.

Offerors that propose telehealth shall follow the appointment procedures and requirements as stated: All telehealth equipment and associated communication devices shall work with approved BOP telehealth communications which utilize a Webex Room. The contractor shall use a provided Webex Room URL to connect to the BOP. If the Contractor's telehealth equipment and network environment complies with Federal IT security standards, the BOP may facilitate a direct IP connection to the provider's telehealth connection point to facilitate IP-to-IP calls. If the direct connection option is used, the Contractor will certify compliance with all applicable Federal policies.

Institution Telehealth Equipment List:	**Number of Items:**
Cisco DX80	1

Telehealth specialty(s) required by the institution.	**Does your firm offer this telehealth specialty in your proposal?**	**In-network facility telehealth physician has privileges at:**	**Will the provider also perform services within an inpatient, outpatient, or office setting? If so, indicate which below.**
1. Tele-triage			
2. Cardiologist			
3. Dermatologist			
4. Endocrinologist			
5. Gastroenterologist			
6. General Surgeon			
7. Neurologist			
8. Nephrologist			
9. Pulmonologist			
10. Rheumatologist			
11. Urologist			
12. Infectious Disease Specialist			
If additional space is needed, include an additional attachment 6-C.			

Proximity of physician offices to the Institution:

Minimum _____ miles Maximum _____ miles

Attestation

Comprehensive Medical Contracts:

To Address ATU Concerns

The vendor affirms that they have security controls in place to protect DOJ information when that data is being stored, transmitted, processed, or displayed on the vendor's information technologies. Applicable security controls include certifications indicating compliance with: state licensure requirements, SOC 2, ISO 27001, Payment Card Industry, HIPAA as applicable or other environment certifications that would be applicable (to be specified by the vendor). **Vendor has attached documentation of said certifications as part of this affirmation.**

The vendor affirms that internal controls are in place to identify and remediate vulnerabilities within any IT system in which DOJ information is stored and that DOJ data will be stored exclusively within the boundaries of the United States and that only US citizens have access to DOJ's data. The vendor affirms that any DOJ information made available to vendor under this contract shall be used only for the purpose of performance of this contract and shall not be divulged or made known in any manner to any persons except as may be necessary in the performance of this contract. The vendor shall neither reproduce nor release such information to any third-party at any time, including during or after performance of the contract, without prior written permission of the CO or COR.

The vendor agrees to report any actual or suspected breach of DOJ Information within one hour of discovery of an actual breach, and within 24 hours of a suspected breach if vendor has not yet been able to determine whether a breach has occurred. A "breach" is an incident or occurrence that involves the loss of control, compromise, unauthorized disclosure, unauthorized acquisition, or any similar occurrence where: (1) a person other than an authorized user accesses or potentially accesses DOJ Information or (2) an authorized user accesses or potentially accesses DOJ Information for an other than authorized purpose. The report of a breach must be made to the CO or COR; if neither can be reached, the vendor must report the breach to the DOJ Security Operations Center (jsoc@usdoj.gov, 202-357-7000) and FBOP's Information Security Program Office; the COR; and the Contracting Officer within one (1) hour of the initial discovery. The vendor should not disclose any details of the potential or confirmed breach to any individual not involved in responding to the breach. The vendor agrees to cooperate with DOJ's inquiry into the incident and efforts to minimize risks to DOJ or individuals. Such cooperation includes, but is not limited to, providing to DOJ full access to any facility and/or Information System affected or potentially affected the breah or potential breach, and to undertake any and all response actions DOJ determines are required to ensure the protection of DOJ Information, including providing all requested images, log files, and event information to facilitate rapid resolution of sensitive information incidents. The vendor further agrees that it shall be responsible for all costs and related resource allocations that DOJ deems required for all such response activities related to any breach.

A. Vendor Information Type Questions

Yes	No	N/A	Description
☐	☐	☐	Is the data sensitive (as defined by NIST)?
☐	☐	☐	Does the data contain Personally Identifiable Information (PII)?
☐	☐	☐	Does the data contain Federal Tax Information (FTI)?
☐	☐	☐	Does the data contain Protected Health Information (PHI)?
☐	☐	☐	Does the data contain other Limited Official Use Information: ☐ Legal Privilege ☐ Legal Strategy ☐ Grand Jury ☐ Title III Information ☐ Protected Materials ☐ Privacy Act ☐ Procurement Sensitive ☐ Intellectual Property ☐ Law Enforcement Sensitive ☐ Infrastructure Sensitive
☐	☐	☐	Approximately how many records will be transmitted to the vendor during the contract period?

B. Vendor Information Security Questions

Yes	No	N/A	Description
☐	☐	☐	Is Multi Factor Authentication (MFA) used to access DOJ data?
			Describe implementation: Explain N/A:
☐	☐	☐	Is the principle of least privilege employed for access management?
			Describe implementation: Explain N/A:
☐	☐	☐	Is sensitive data encrypted at rest and/or in transit (e.g., sensitive Personally Identifiable Information (PII), Federal Tax Information (FTI), health information (HIPAA))?
			Describe implementation: Explain N/A:
☐	☐	☐	Do portable devices require mobile device management tools before allowing access to corporate data, including email?
			Describe implementation: Explain N/A:
☐	☐	☐	Is there a formal cyber security program which includes policy enforcement?
			Describe implementation: Explain N/A:
☐	☐	☐	Are routine vulnerability scans of all system assets and endpoints performed?

Yes	No	N/A	Description
			Describe implementation: Explain N/A:
☐	☐	☐	Are internal and external penetration tests conducted?
			Describe implementation: Explain N/A:
☐	☐	☐	Are known vulnerabilities mitigated or remediated within 30 for critical and high risk, and 90 days for medium risks?
			Describe implementation: Explain N/A: o Critical Patch - to be installed within 30 days or sooner if possible o High Risk Patch - to be installed within 60 days or sooner if possible o Medium Risk Patch - to be installed within 90 days or sooner if possible o Low Risk Patch - to be installed within the normal patching rotation, but within at least a year.
☐	☐	☐	Are monitoring services employed which will notify resources as needed 24x7x365 to support incident response?
			Describe implementation: Explain N/A:
☐	☐	☐	If sub-contractors are used, describe questionnaire and other requirements of sub-contractors: Describe implementation: Explain N/A:

C. Data Owners

Role	Responsible Party	Responsibilities
Data Steward		Entity who is responsible for the categorization, protection, usage, and quality of the data.
Data Steward		Entity who is responsible for the confidentiality, integrity, and availability of the data on a day-to-day basis.
Data Steward		Entity who is responsible for the confidentiality, integrity, and availability of data on a day-to-day basis.

D. Vendor Signature

	As the vendor representative, I attest that the information in sections A and B are accurate, and I accept the responsibility of protecting and ensuring the confidentiality, integrity, and availability of DOJ data on a day-to-day basis when it is on the vendor or subcontracted vendor networks.

The Medical Claims Adjudication contractor will need the following data elements for each type of provider in your proposed network. Each provider record should be stored in the file as comma separated values (CSV) in a single row. A new row is created for each provider record.

Please note that there are three different file formats to submit depending on the type of provider(s) in your network:

1) For Institutional Providers

Field Number	Field Name	Maximum Length	Notes	Example
1	National Provider Identifier (NPI) Number	10		9876543210
2	Institution Name	70		XYZ Medical Center
3	Doing Business As (DBA) Name	70	Leave blank if not applicable.	XYZ Hospital Trust
4	EIN (Tax ID) Number	9	Enter as 9 digits with no dashes.	987654321
5	Mailing Address (Form W-9 Address)	55	Use the address found on the Form W-9.	PO Box 174256
6	Mailing City	40	Use the city found on the Form W-9.	Los Angeles
7	Mailing State	2	Use the state found on the Form W-9. Two-character abbreviation only.	CA
8	Mailing Zip Code	5	Use the zip code found on the Form W-9. Only 5 digits needed.	90001
9	Healthcare Provider Taxonomy Code	10	Lookups of provider taxonomy codes can be performed on: https://taxonomy.nucc.org/	282N00000X
10	Healthcare Provider Taxonomy Name	70	Lookups of provider taxonomy codes can be performed on: https://taxonomy.nucc.org/	General Acute Care Hospital

Sample CSV file record using the example data from above:

9876543210,XYZ Medical Center,XYZ Hospital Trust,987654321,PO Box 174256,Los Angeles,CA,90001,282N00000X,General Acute Care Hospital

2) For Individual Practitioners (Sole Providers)

Field Number	Field Name	Maximum Length	Notes	Example
1	National Provider Identifier (NPI) Number	10		11223344550
2	Provider Last Name	35		Johnson
3	Provider First Name	20		Richard
4	Provider Middle Initial	1		L
5	Provider Suffix Text	7		Sr, DO
6	EIN (Tax ID) or SSN Number	9	Enter as 9 digits with no dashes.	102030405
7	Physical Address	55	Address of the office or facility.	1111 Main Street
8	Physical City	40	City of the office or facility.	Washington
9	Physical State	2	State of the office or facility. Two-character abbreviation only.	DC
10	Physical Zip Code	5	Zip code of the office of facility. Only 5 digits needed.	20024
5	Mailing Address	55	If different than physical address.	P.O. Box 1718
6	Mailing City	40	If different than physical address.	Washington
7	Mailing State	2	If different than physical address.	DC
8	Mailing Zip Code	5	If different than physical address.	20001
9	Healthcare Provider Taxonomy Code	10	Lookups of provider taxonomy codes can be performed on: https://taxonomy.nucc.org/	207RG0100X
10	Healthcare Provider Taxonomy Name	70	Lookups of provider taxonomy codes can be performed on: https://taxonomy.nucc.org/	Gastroenterology Physician

Sample CSV file record using the example data from above:

1122334455,Johnson,Richard,L,”Sr, DO”,102030405,1111 Main

Street,Washington,DC,20024,P.O.
Box,1718,Washington,DC,20001,207RG0100X,Gastroenterology Physician

3) Group Practices and Suppliers (please note, create a record for each rendering physician in the group who could treat BOP patients)

Field Number	Field Name	Maximum Length	Notes	Example
1	Group National Provider Identifier (NPI) Number	10		99887766550
2	Group Name	35		ABC Orthopedic Trauma Surgery
3	Group Healthcare Provider Taxonomy Code	10	Lookups of provider taxonomy codes can be performed on: https://taxonomy.nucc.org/	193400000X
4	Group Healthcare Provider Taxonomy Name	70	Lookups of provider taxonomy codes can be performed on: https://taxonomy.nucc.org/	Single Specialty Group
5	Rendering Provider National Provider Identifier (NPI) Number	10	Be sure to create a record for each rendering physician in the group who may treat BOP patients.	55555222221
6	EIN (Tax ID) or SSN Number (group)	9	Enter as 9 digits with no dashes.	102030405
7	Rendering Provider Last Name	35		Smith
8	Rendering Provider First Name	20		Melanie
9	Rendering Provider Middle Initial	1		K
10	Rendering Provider Suffix Text	7		MD
11	Physical Address	55	Address of the office or facility.	1234 River Road
12	Physical City	40	City of the office or facility.	Roseville
13	Physical State	2	State of the office or facility. Two-character	CA

			abbreviation only.	
14	Physical Zip Code	5	Zip code of the office of facility. Only 5 digits needed.	95747
15	Mailing Address	55	If different than physical address.	
16	Mailing City	40	If different than physical address.	
17	Mailing State	2	If different than physical address.	
18	Mailing Zip Code	5	If different than physical address.	
19	Rendering Provider Healthcare Provider Taxonomy Code	10	Lookups of provider taxonomy codes can be performed on: https://taxonomy.nucc.org/	207XX0801X
20	Rendering Provider Healthcare Provider Taxonomy Name	70	Lookups of provider taxonomy codes can be performed on: https://taxonomy.nucc.org/	Orthopedic Surgery Orthopedic Trauma

Sample CSV file record using the example data from above:

9988776655,ABC Orthopedic Trauma Surgery,193400000X,Single Specialty Group,55555222221,102030405,Smith,Melanie,K,MD,1234 River Road,Roseville,CA,95747,,,,,207XX0801X,Orthopedic Surgery Orthopedic Trauma

1. Medical claims shall be transmitted in accordance with regulatory and industry standards for the submission of ANSI 837 transactions. The contractor shall be responsible for maintaining its information system(s) so that it remains compliant with such regulatory and industry standards. Any system changes that are required by the Bureau of Prisons (BOP)'s medical claims adjudicator that are not the result of a regulatory or industry-wide change shall be negotiated on a case-by-case basis.

2. Medical claims may be submitted electronically via the claims clearinghouse service of the contractor's choosing to the payer code BOPMC which has been registered with the claims clearinghouse networks. As an alternative, the Medical Claims Adjudication contractor can also provide access to a web portal allowing uploading of ANSI 837 claim files or direct data entry of BOP claims if desired.

3. Each medical claim, whether submitted electronically or in hard copy, shall identify the Inmate by his/her individual BOP Inmate register number and shall reflect the patient's relationship to insured as "self." The Inmate number shall be keyed with five digits, a hyphen, and three digits in the following format: 12345-678. In an electronically transmitted medical claim, this information shall be keyed at 2010BA NM109 for both facility and professional medical claims. In a UB-04 institutional hardcopy medical claim, the BOP Inmate register number shall be included in the Insured's Unique ID field block 60. In a CMS-1500 professional hardcopy medical claim, the BOP Inmate register number shall be included in the Insured's I.D. Number field, block 1a.

4. Each medical claim, whether submitted electronically or in hard copy, shall identify the invoice number under which the individual medical claim is being invoiced. In an electronically transmitted medical claim, the invoice number shall be referenced in the Patient Account Number field submitted in the 2300 loop, CLM01 segment. In a UB-04 hardcopy medical claim submission, the invoice number shall be included in the Patient Control Number field, block 3a. In a professional hardcopy medical claim submission, the invoice number shall be included in the Patient Account Number Field, block 26. The invoice number shall be limited to 13 characters. Positions 1-3 will be the institution's alpha facility code, positions 4-5 will be alpha/numeric and mutually agreed upon by the institution and contractor, and positions 6-13 will be alpha/numeric and sequential. Not all positions, 6-13, must be used. No special characters will be allowed.

5. The institution's 3-character alpha Facility Code will be transmitted in electronically submitted medical claims (either 837i or 837p format) in the Subscriber Group or Policy Number Field in the 2000B Loop, SBR03 segment. In a UB-04 institutional hard copy medical claim, the Institution Facility Code will be included in the Insurance Group No Field, block 62. In a CMS-1500 professional hardcopy medical claim, the Institution Facility Code will be included in the Insured's Policy, Group, or FECA Number Field, block 11. An example of the Facility Code(s) in use at BOP facilities in include:

    - WIL Williamsburg FCI
    - WIL Williamsburg SCP

6. The Medical Claims Adjudication Contractor will perform automated validation of any NPI numbers received on a BOP claim at the EDI Gateway.

   If a claim is received from a CMC with a NPI number that is not currently in their Provider Data Submission, the claim will be automatically rejected at the EDI Gateway.

   A CA277 Claims Acknowledgement message will be received with a Claim Status Code of "A7" and a Claim Status Category Code of "562" in the STC segments on the report explaining the rejection of the claim(s) due to missing or invalid NPI numbers.

   The following fields on an 837i institutional claim or an 837p professional claim which could or must contain a valid NPI number within the Provider Data Submission will be checked:

   I. 837i:
      1. 2010AA NM109 Billing Entity Identification Code (required)
      2. 2010AB NM109 Pay-To Provider Identification Number Code
      3. 2310A NM109 Attending Provider Identification Code (required)
      4. 2310B NM109 Operating Physician Identification Code
      5. 2310C NM109 Other Operating Physician Identification Code
      6. 2310E NM109 Service Facility Identification Code
      7. 2420A NM109 Operating Physician Identification Code
      8. 2420B NM109 Other Operating Physician Identification Code

   ii. 837p:
      1. 2010AA NM109 Billing Provider Identification Code (required)
      2. 2310A NM109 Referring Physician Identification Code
      3. 2310B NM109 Rendering Physician Identification Code (required)
      4. 2310C NM109 Service Facility Location Identification Code (required)
      5. 2310D NM109 Supervising Provider Name Identification Code
      6. 2420A NM109 Rendering Provider Identification Code
      7. 2420B NM109 Purchased Service Provider Identification Code Qualifier

7. Paper medical claims submitted to the medical claims adjudicator shall be mailed to the following address:

   Mailing:

   Apprio Inc.
   c/o BOP Medical Claims Adjudication Program
   3191 Maguire Blvd. Suite 100
   Orlando, FL 32803

Federal Bureau of Prisons

National Formulary Part 1

Approved:

ELIZABETE STAHL

Digitally signed by ELIZABETE STAHL
Date: 2025.08.27 07:44:10 -04'00'

Dr. Elizabete Stahl, DO, Medical Director

Federal Bureau of Prisons
National Formulary Part 1 Summer 2025

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Federal Bureau of Prisons
National Formulary Part 1 Summer 2025

Summary of Formulary Changes: Summer 2025 Meeting

The prescribing of medications against the restrictions of the national formulary, without an approved non-formulary request, is considered an unauthorized use of government funds. The procurement of non-formulary medications or the procurement of formulary medications used outside of formulary restrictions is considered an unauthorized procurement. The prescriber is responsible for justifying a non-formulary request.

The following is a summary of the major changes resulting from the Summer 2025 Bureau of Prisons (BOP) Formulary Meeting. Revisions or changes from the previous year are highlighted in yellow throughout this document.

Topic	Final Actions
Alemtuzumab (Lemtrada®)	**ADD** non-formulary use criteria
Ambrisentan (Letairis®)	**ADD** non-formulary use criteria
Amoxicillin/Clavulanate ER (Augmentin XR®)	**DELETE** advisory **ADD** non-formulary use criteria
Antihemophilic Factor IX (Alprolix®, Benefix®, Profilnine®, Rebinyn®)	**ADD** non-formulary use criteria
Antihemophilic Factor VIIa (NovoSeven®, Sevenfact®)	**ADD** non-formulary use criteria
Antihemophilic Factor VIII (Advate®, Afystla®, Eloctate®, Esperoct®, Kogenate®, Kovaltry®, Novoeight®, Nuwiq®, Recombinate®)	**ADD** non-formulary use criteria
Antihemophilic Factor VIII (Koate®)	**DELETE** **ADD** non-formulary use criteria
Antihemophilic Factor VIII (Xyntha)	**DELETE** **ADD** non-formulary use criteria
Antihemophilic Factor VIII – VWF (Alphanate®)	**DELETE** **ADD** non-formulary use criteria
Antihemophilic Factor VIII – VWF (Humate®, Wilate®)	**ADD** non-formulary use criteria
Aripiprazole lauroxil ER (Aristada INITIO®)	**DELETE** **ADD** non-formulary use criteria
Bosentan (Tracleer®)	**ADD** non-formulary use criteria
Choline fenofibrate (Trilipix®)	**ADD** with inclusionary diagnoses
Cladribine (Mavenclad®)	**ADD** non-formulary use criteria
Colestipol (Colestid®)	**ADD** inclusionary diagnoses
Dimethyl fumarate (Tecfidera®)	**ADD** non-formulary use criteria
Diroximel fumarate (Vumerity®)	**ADD** non-formulary use criteria
Emicizumab (Hemlibra®)	**ADD** non-formulary use criteria
Epoprostenol (Flolan®, Veletri®)	**ADD** non-formulary use criteria
Famotidine (Pepcid®)	**ADD**
Fenofibrate micronized (Antara®, Lofibra®)	**ADD** with inclusionary diagnoses
Fenofibrate non-micronized (Lipofen®)	**DO NOT ADD**
Fingolomid (Gilenya®)	**ADD** with inclusionary diagnoses

Gabapentin (Neurontin®)	**ADD** with inclusionary diagnoses **RETAIN** directly-observed therapy requirement
Glatiramer acetate (Copaxone®)	**ADD** with inclusionary diagnoses
Iloprost (Aurlmyn®, Ventavis®)	**ADD** non-formulary use criteria
Insulin glargine (Lantus®)	**ADD**
Interferon beta-1a (Avonex®, Ribif®)	**ADD** non-formulary use criteria
Interferon beta-1b (Betaseron®, Extavia®)	**ADD** non-formulary use criteria
Ipratropium nasal spray (Atrovent®)	**ADD** 30-day restriction **ADD** inclusionary diagnoses
Lactulose solution	**ADD** inclusionary diagnosis
Macitentan (Opsumit®)	**ADD** non-formulary use criteria
Mitoxantrone (Novantrone®)	**ADD** non-formulary use criteria
Monomethyl fumarate (Bafiertam®)	**ADD** non-formulary use criteria
Natalizumab (Tysabri®)	**ADD** non-formulary use criteria
Ocrelizumab (Ocrevus®)	**ADD** non-formulary use criteria
Ofatumumab (Kesimpta®)	**ADD** non-formulary use criteria
Ozanimod (Zeposia®)	**ADD** non-formulary use criteria
Paliperidone palmitate ER (Invega Sustenna®)	**DELETE** **ADD** non-formulary use criteria
Paliperidone palmitate ER (Erzofri®)	**ADD** non-formulary use criteria
Paliperidone palmitate ER (Invega Trinza®)	**UPDATE** non-formulary use criteria
Paliperidone oral (Invega®)	**ADD**
Paliperidone palmitate ER (Invega Halfyera®)	**ADD** non-formulary use criteria
Pegylated interferon beta-1a (Plegridy®)	**ADD** non-formulary use criteria
Ponesimod (Ponvory®)	**ADD** non-formulary use criteria
Riociguat (Adempas®)	**ADD** non-formulary use criteria
Rituximab-abbs (Truxima®)	**DELETE**
Selexipag (Uptravi®)	**ADD** non-formulary use criteria
Sildenafil (Revatio®)	**ADD** non-formulary use criteria
Siponimod (Mayzent®)	**ADD** non-formulary use criteria
Sotatercept (Winrevair®)	**ADD** non-formulary use criteria
Tadalafil (Adcirca®)	**ADD** non-formulary use criteria
Teriflunomide (Aubagio®)	**ADD** with inclusionary diagnoses
Tiotropium (Spiriva Handihaler®)	**RETAIN**
Treprostinil (Remodulin®)	**ADD** non-formulary use criteria
Tricyclic Antidepressants	**DELETE** advisory **ADD** formulary requirement “requires crushing” **UPDATE** order duration
Ublituximab (Briumvi®)	**ADD** non-formulary use criteria
Umeclidinium (Incruse®)	**ADD** with inclusionary diagnoses

National BOP Formulary Mission and Procedural Statement

Purpose

A formulary system, as defined in ASHP Statement on the Formulary System, is the ongoing process through which a health care organization establishes practices "…on the use of drugs, therapies, and drug-related products and identifies those that are most medically appropriate and cost-effective to best serve the health interests of a given population."

The BOP formulary is a list of medications that are considered by the organization's professional staff to ensure high-quality, cost-effective drug therapy for the population served. Participants of the Pharmacy, Therapeutics and Formulary Meeting are responsible for the development, maintenance, and approval recommendations of the formulary to the BOP Medical Director. Periodically, medications are reassessed and extensively reviewed for inclusion in, exclusion from, or restrictions in the formulary as applicable per current evidence-based practices and security concerns.

Regular maintenance of the BOP formulary ensures optimal treatment options are uniformly and readily available.

The primary goals of BOP formulary management are to optimize therapeutic outcomes, optimize cost effectiveness of medications, and ensure medication use is conducive within the correctional environment.

Non-Formulary Request Expectations

1. ALL BOP institutions, including medical centers, are expected to abide by the formulary as outlined in the BOP Pharmacy Services Program Statement. It is expected that for non-urgent requests, persons in the review process will NOT be circumvented in the event of a short-term absence for non-urgent requests.
2. ALL comments made on the request are expected to be medically appropriate and of a nature conducive to being placed in the medical record.
3. It is expected that non-urgent non-formulary medications will not be initiated until AFTER authorization is received, even if the medication is on the shelf from a previous request. Doing so can be deemed an unauthorized procurement.
4. Prescribers (BOP Physician / APPs / Dentist/ Clinical Pharmacist) are expected to thoroughly justify the request, including why the formulary agent cannot be used, and provide pertinent laboratory information. It is expected that non-formulary use criteria will be thoroughly addressed point by point and that all non-formulary use justifications/criteria are met.
5. Clinical Directors (CDs) are expected to support the BOP National Formulary and ensure compliance at their respective institutions. The CD is expected to review all requests, ensuring that appropriate justifications and corresponding non-formulary use criteria are met. It is expected that the CD will allow the pharmacist to appropriately comment and provide pertinent information on the request even if not supportive. It is expected that the CD will disapprove, at the local level, any request that does not meet the non-formulary use criteria.

6. Institution Chief Pharmacists are expected to review all medication orders for formulary compliance. This will include reviewing all non-formulary requests for completeness and appropriate justification and, if applicable, commenting on information provided by the prescriber regarding non-formulary use criteria. The pharmacist is expected to provide pertinent information regarding patient compliance with formulary agents, drug cost information, and other comments as applicable to the request.
7. Institution administration (Health services administrator (HSA), Associate Warden, and Warden) are expected to support and ensure compliance with the BOP National Formulary. Administrative decisions regarding medical care are expected to be consistent with the BOP National Formulary and not conflict with the medically necessary provision of medications and restrictions set forth in the BOP National Formulary.
8. Consultant Physicians are expected to utilize and stay within the guidelines of the BOP National Formulary when making recommendations and to provide specific and adequate justification if formulary medications cannot be used.
9. Court orders recommending or ordering specific treatments should be referred to the appropriate BOP attorney(s). All such orders/recommendations are still subject to the non-formulary request process.
10. It is expected that all institution inventories and ordering procedures will be conducive to acceptable inventory practices (e.g. two week par levels on the shelf maintained with, at minimum, weekly medication ordering).

Compliance

1. Completion and appropriateness of non-formulary medication requests are elements of the Clinical Director's peer review process.
2. The Medical Director may request Regional Medical Director follow-up and/or issue a memo to the CD requesting a response and corrective action if problems are identified. This may be prompted by consistent failure of the institution staff to appropriately initiate or complete all elements of non-formulary medication requests, particularly the required supporting documentation.
3. The Medical Director may issue memos to the institution Warden regarding persistent problems or concerns with respect to the institution's compliance with this process.

Continuity of Care Provision

There are times when patients are processed into a facility after normal working hours, weekends, and holidays. In these cases, continuation of non-formulary medications prior to approval may be medically necessary because of the following reasons:

1. There is no formulary substitute or changing to a formulary substitute will not allow for appropriate follow up monitoring until the next workday, **AND**
2. Not providing the medication would pose a significant risk to the patient.

When continuation of a non-formulary medication prior to approval is medically necessary, an allowance is given to dispense/administer the medication for 4 days while awaiting approval. **This 4-day allowance is to only be utilized for urgent continuity of care purposes and not for the purpose of initiating routine/non-emergency non-formulary medications without appropriate approval.**

This provision is not a substitute for adequate follow up, monitoring, and initiation of approved non-formulary medications for patients maintained within the facility for chronic ongoing conditions. It is the prescriber's

responsibility to ensure submission of a non-formulary request prior to expiration of a currently approved non-formulary request.

Medication orders that do not meet the above criteria for continuity-of-care should not be written, entered into the pharmacy software system, or dispensed prior to appropriate non-formulary request approval.

Definitions & Rules

Formulary Rules

1. Brand name products are for reference only
2. The least expensive generic and/or biosimilar product is to be utilized, when available. Otherwise, non-formulary approval is required.
3. Use against specific restrictions (i.e., directly observed therapy required, crush, etc.) requires non-formulary approval.
4. Use of a formulation not specifically included in the national formulary (e.g., extended release, nasal, topical, ophthalmic, rapid dissolve tablet, combination product) is not authorized and requires non-formulary approval.

Compounding

Compounding is defined as the combining, mixing, or altering of ingredients by a pharmacist in response to a physician's prescription to create a medication tailored to the needs of an individual patient. All compounded prescription drugs are deemed "new drugs" under the Federal Food, Drug, and Cosmetic Act (FDCA).

ALL compounded medications are considered non-formulary and will go through the same non-formulary and addition to formulary processes as individual, commercially available medications.

DEA Controlled Substances

1. All controlled substances are restricted to directly observed therapy.
2. Immediate release, non-enteric coated, oral controlled substances are to be crushed prior to administration.
3. Immediate release controlled substance capsules should be pulled apart and administered in powder form.

Directly Observed Therapy ("Pill Line") Only

"Directly observed therapy only" is a restriction placed on controlled substances, some psychotropics, tuberculosis (TB) medications, and some other drugs requiring that a single dose of the drug be administered to a patient by a qualified employee at a designated time and place. The administration of that dose must be recorded in a Medication Administration Record (MAR) by the employee. A report of medications that are restricted to directly observed therapy only is available in the BOP electronic medical record (BEMR). Some medications are designated as directly observed therapy only for only certain indications (see National Formulary Part II for details).

Epinephrine Auto-Injector (EpiPen®)

EpiPen® may be issued to patients with known anaphylaxis utilizing the procedure outlined below.

1. Epipen® is to be entered into BEMR as a directly observed therapy item with the recommended sig: - "Inject as directed for severe allergic reaction **must present this device to pill-line daily for integrity inspection**"
2. The patient will present the Epipen® at pill line every day to insure the seal is intact and that no manipulation has occurred.
3. Health services staff will document the encounter in the Medication Administration Record daily.

4. The patient should be counseled regarding the potential consequences and adverse actions that may occur if tampering is evident or the product is lost or manipulated.

Icatibant Acetate Auto-Injector (Firazyr®)

1. Orders for icatibant acetate injection (Firazyr®) will be entered into BEMR as DOT.
2. The following statement will appear on the label after the directions: **must present device and needle to pill line daily for integrity inspection**
3. Compliance with daily integrity inspection will be monitored.
4. Patient should be counseled regarding potential adverse actions if tampering is evident or product is lost or manipulated.
5. Staff education will be provided to facilitate these procedures.
6. Any needed local procedural changes will be made to facilitate these procedures.

Multi-Dose Single-Patient Pens (semaglutide, insulin, etc.)

Multidose, single-patient injection pens may be issued to patients utilizing the procedure outlined below.

1. The injection pen medication order is processed as Directly Observed Therapy with the BEMR directions: ***must present this device to pill-line [weekly, daily, etc.] for integrity inspection***
2. When a dose is due, patients will return to the health service department for a new pen needle, self-inject, and immediately dispose of the needle appropriately under staff supervision
3. Pen needles will not be dispensed to patients and will be controlled and inventoried according to policy.

FDA Medication Guides and Side Effects Statement

FDA WEBSITE: http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm

Provision of FDA medication guides and display of the side effects statement ARE NOT required when the patient is:

1. Confined within a BOP institution.
2. Being transferred within the BOP (intra-system) or to another correctional entity (inter-system).

FDA medication guides and display of the side effects statement ARE required to be provided to the patient when the patient is:

1. Being released to the community (including writs and furloughs)
2. Sent to a Residential Reentry Center (RRC) (e.g., halfway house).

Over the Counter Medications

Over the counter (OTC) medications may only be prescribed as a maintenance medication when treatment is medically necessary and associated with ongoing follow-up in a chronic care clinic. Per Program Statement 6541.02 Over-the-Counter Medications, during institution triage / sick call, medical staff will refer patients to the commissary in response to complaints related to cosmetic and general hygiene issues or symptoms of minor ailments.

Medical Center Only

Medical center only is a restriction placed on some medications requiring that the drug only be used within a Federal Medical Center.

Medication Restrictions

Medication restrictions are prescribing restrictions placed on certain medications. Variance from restrictions requires non-formulary authorization.

MLP Requires Cosign

"MLP requires cosign" is a restriction placed on some medications requiring that a physician sign the medical record each time the drug is prescribed. Subsequent medication orders for the drug must also include the signature of a physician.

Placebos – Statement on Use

Placebos will not be utilized within the Federal Bureau of Prisons.

References:

1. **American Medical Association:** "In the clinical setting, the use of a placebo without the patient's knowledge may undermine trust, compromise the patient-physician relationship, and result in medical harm to the patient."
2. **American Society of Health-System Pharmacists:** " . . . the use of placebos in clinical practice is ethically acceptable only when patients have been informed of and agree to such use as a component of treatment . . . ."

Look-Alike/Sound-Alike Medications

Both The Joint Commission (JC) and the Accreditation Association for Ambulatory Health Care (AAAHC) require health care organizations to identify look-alike/sound-alike medications utilized at their site. A look-alike/sound-alike medication list is available from the Institute for Safe Medication Practices (ISMP).

BOP institutions must incorporate look-alike/sound-alike drugs into the agendas of local Pharmacy and Therapeutics Committee Meetings and review them on an annual basis. Discussions, decisions, and local policy must follow the requirements set forth by accrediting bodies (JC, AAAHC).

This responsibility is deferred to the local level owing to the varying functions of our institutions (e.g., medical referral centers, ambulatory institutions, detention centers, implementation of levels of care) and the fact that not all institutions carry the same items from the BOP National Formulary.

Resources:

1. The Joint Commission, http://www.jointcommission.org.
2. Institute for Safe Medication Practices (ISMP), https://www.ismp.org/.
3. ISMP, "List of Confused Drug Names,"https://home.ecri.org/blogs/ismp-resources/list-of-confused-drug-names
4. The Accreditation Association for Ambulatory Health Care, https://www.aaahc.org/.

Risk Evaluation and Mitigation Strategies (REMS)

Risk Evaluation and Mitigation Strategies (REMS) are defined by the FDA as programs for managing a known or potential serious risk associated with a drug or biologic product. Medications with a REMS designation require increased levels of monitoring and control, with the most extreme requiring written contracts between the pharmacy/physician and the manufacturer.

Institution pharmacists and physicians should not sign any agreements without review by the BOP chief pharmacist or a designee. The BOP chief pharmacist / designee will consult with the BOP Office of General Counsel as appropriate. A list of current REMS drugs can be found at http://www.accessdata.fda.gov/scripts/cder/rems/index.cfm.

BOP institutions with patients requiring "specialty pharmacy restricted REMS medications" (e.g., Revlimid®) should contact their regional chief pharmacist or the chief of pharmacy logistics support for guidance. Institutions may be directed to obtain certain complex REMS medications from a single BOP pharmacy. Institutions and providers should not obtain REMS medications from a non-BOP pharmacy until all internal processes are exhausted and Central Office Pharmacy staff have instructed them to do so.

All medications which require REMS program enrollment will include the non-formulary use criteria “Request must include confirmation of REMS enrollment.”

Keep On Person (KOP), Self-Carry Medications

Medications are generally excluded (i.e., not Keep On Person (KOP) / self-carry eligible) if:

1. Potential for abuse or misuse (e.g., controlled substances)
2. Injectable drugs (except for those specifically permitted by the National Formulary)
3. Close monitoring required (e.g., TB meds)
4. Caustic or harmful agents (e.g., podofilox)
5. Refrigeration required
6. Potential for misuse of packaging (e.g., glass container, inhalers with piercing devices)
7. Cost

Clinical Review Elements

Select formulary medications may require clinical review to ensure safe and effective utilization. Clinical review elements are intended to prompt the exchange of information pertinent to patient-specific cases with the goal of improving care.

Formulary with Clinical Review Elements

Methadone (Dolophine®)

In the treatment of Opioid Use Disorder, the following clinical review elements apply:

1. Intake:
    a. Receipt of methadone for treatment of opioid use disorder has been confirmed by the prior OTP through outside medical records or contact with the prior OTP.
    b. Ordering provider must have ordering rights for methadone or a TO/VO has been obtained from a provider with methadone ordering rights.
    c. For continuation upon intake, request will be approved by Regional Chief Pharmacist for 30 days pending initial evaluation if appropriate.
2. Initiation:
    a. Patient has documented diagnosis of opioid use disorder and/or opioid dependence.
    b. Ordering provider must have ordering rights for methadone.
    c. Documentation in BEMR of plans for continuity of care after release.
    d. Must also meet at least one of following:
        i. Patient is pregnant and prefers use of methadone over buprenorphine.
        ii. Patient has clearly documented serious allergy and/or side effect to buprenorphine in the FBOP.
        iii. Patient has clearly documented failure (e.g., severe opioid cravings, objective signs of opioid withdrawal, and/or continued use of illicit opioids to supplement treatment, etc.) in the FBOP with consistent compliance with the following:
            1. Buprenorphine sublingual up to 24 mg daily > 2 months.
            2. Appropriate dosing of long-acting buprenorphine injection > 4 months.

Non-Formulary Use Criteria / Justification Requirements, and Algorithms

Acitretin (Soriatane®)

1. Patients need to have a significant BSA involvement, failed appropriate topical agents, and either failed methotrexate or is a poor candidate for methotrexate.
2. The patient has a dermatology consult in BEMR with a dermatologist.
3. Female patients must meet all criteria of the "Do our P.A.R.T" program; however, alternative medications should be sought due to the teratogenicity and long-term effects of acitretin.

Abrocitinib (Cibinqo®)

1. Patient has been diagnosed with moderate to severe atopic dermatitis by a dermatologist AND
2. Self-management with fragrance-free moisturizers has been tried for at least 6 continuous weeks without symptom improvement AND
3. Patient has a contraindication to, intolerability to, or have failed at least 12 weeks of treatment with at least ONE medication in EACH of the following categories: AND
    a. High potency/class 1 topical corticosteroids
    b. Topical calcineurin inhibitor
4. Patients has an allergy, documented intolerance, or failure with an adequate trial of dupilumab or tralokinumab.
5. If all other criteria are met, the least costly biologic for the requested indication at the time of request will be approved.

Adalimumab (Humira®and biosimilars)

1. Adalimumab is recommended agent before etanercept and golimumab due to better side effect profile and cost effectiveness.
2. Failure of an adequate trial of maximally dosed/tolerated methotrexate/prednisone or other formulary non-biologic DMARDs.
3. Intolerable side effects of methotrexate where a TNF agent may allow a decrease in methotrexate dose.
4. All new and renewal prescriptions require consultation with an appropriate specialist based on the disease state being treated (for example, dermatologist, gastroenterologist, or rheumatologist). Consult must be uploaded in BEMR.
5. Requests for patients with a TST > or = 5mm or positive IGRA (interferon gamma release assay) test must be accompanied by evidence of LTBI treatment completion (medication used with ingested dose counts). TST or IGRA must be repeated yearly.
6. Initial requests must include HBV/HCV serology for prior evidence of hepatitis infection.
7. For chronic plaque psoriasis:
    a. Request includes documented percent of affected BSA % AND
    b. Patient has failed of an adequate trial of a clinically indicated formulary non-biologic agent AND
    c. $\geq$ 10% BSA is affected (Severe CPP) OR
    d. At least $\geq$ 5% of BSA (Moderate CPP) AND crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.

e. NFR renewals must include documentation of improved symptoms (% BSA impacted)
f. Patients with mild CPP may be managed with formulary topical treatments.

Alirocumab (Praluent®) – See PCSK9 inhibitors

Alogliptin (Nesina®) – See Dipeptidyl peptidase-4 (DPP-4) inhibitors

Alemtuzumab (Lemtrada®)

1. Prescribed by, or in consultation with, a neurologist or other appropriate specialist for the treated disease state.
2. Confirmed diagnosis of relapsing forms of multiple sclerosis – including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
3. Failure (or use contraindicated) of formulary options or justification why formulary options cannot be used.

Ambrisentan (Letairis®)

1. Patient is under the care of a specialist for the treatment of pulmonary hypertension AND
2. Patient is prescribed a phosphodiesterase-5 inhibitor, unless contraindicated or not tolerated.
3. Requests for endothelin receptor antagonists will be approved for ambrisentan, unless justification is provided for why this agent cannot be used.

Amoxicillin/Clavulanate ER (Augmentin XR®)

1. Patient has acute bacterial rhinosinusitis AND one of the following risk factors for severe disease
    a. living in regions where resistant S. pneumoniae >10%;
    b. hospitalization in the last 3 months;
    c. multiple co-morbidities (i.e. chronic cardiac, liver, or kidney disease);
    d. severe infection (e.g. evidence of systemic toxicity or concern for suppurative complications).

Amphetamine w/ or w/o dextroamphetamine (Adderall®, Adzenys ®, Dexedrine®, Dyanavel®, Evekeo ®, Mydayis®, Zenzedi®)

1. Patient has documented diagnosis of ADHD.
2. Psychotherapy, with psychology referral to include individual therapy to learn coping, organizational, prioritization, and anger management skills for a minimum of 6 months. Psychotherapy should continue if medication is initiated. (Concurrent treatment recommended rather than sequential treatment.)
3. Failure of ALL non-stimulant agents after ADEQUATE trials for each step for a minimum of 6 weeks. Patient self-reported trials of medication regimens and doses will not be accepted. All medications trials must have occurred and been documented within the BOP.
    a. Atomoxetine
    b. Atomoxetine plus guanfacine
    c. Atomoxetine plus clonidine
    d. Desipramine +/- atomoxetine
    e. Clonidine
    f. Bupropion
4. Submitted documentation must include/show the following:
    a. Copy of full psychiatric and psychological behavioral function evaluations

   b. Evidence (with specific examples) of inability to function in the correctional environment (e.g., incident reports)
   c. Doses of formulary medications have been maximized
   d. Six-week minimum trial of medication occurred at maximized dose
   e. Assessment for history of drug misuse including type of drug (e.g., stimulant, opiate, benzodiazepine)
5. If stimulant use approved, recommend utilizing methylphenidate immediate-release formulation as opposed to mixed amphetamine salts immediate-release formulation due to methylphenidate's shorter half-life. Requests for long-acting stimulants will not be approved.
6. The use of stimulants in persons with a history of stimulant drug misuse will not be approved.
7. For narcolepsy: Documented verification of the patient's report, to include polysomnography obtained and provided.
8. For narcolepsy: Patient has failed non-pharmacologic management strategies.
9. For narcolepsy: Functional impairment with work assignment, institution security, academic needs.
10. For narcolepsy: Failed treatment with modafinil and fluoxetine (for cataplexy).

Amantadine (Symmetrel®)

1. Drug-induced extrapyramidal reactions not responsive to trihexyphenidyl or benztropine.

Amantadine ER (Osmolex®ER, Gocovri®)

1. Failure of, or contraindication to, immediate release amantadine.

Ammonium lactate lotion/cream

1. Requests to improve appearance of skin will be disapproved.
2. Patient is indigent AND treatment is medically necessary. Orders are limited to 30 days in duration when approved on the basis of indigent status alone. If renewed, indigent status will be reassessed.

Analgesics topical: salicylate / menthol (Bengay®)

1. Failed 30 day trial of oral NSAIDs or NSAIDs are contraindicated *AND*
2. Documented improvement in functional status (required for renewals) *OR*
3. Patient is indigent AND treatment is medically necessary. Orders are limited to 30 days in duration when approved on the basis of indigent status alone. If renewed, indigent status will be reassessed.

Anticoagulants: dabigatran (Pradaxa®), edoxaban (Savaysa®), rivaroxaban (Xarelto®)

1. Contraindication to or treatment failure on apixaban (Eliquis®) or warfarin.

Antifungals (topical): clotrimazole, miconazole, terbinafine, tolnaftate

1. Patient is indigent, treatment is medically necessary, AND has failed OTC Indigent program alternatives (ex: tolnaftate cream). Orders are limited to 60 days in duration when approved on the basis of indigent status alone. If renewed, indigent status will be reassessed.

Antihemophilic Agents (all brands and formulations)

1. Must be prescribed by an appropriate specialist (such as a hematologist) AND
2. Confirmed that the agent is being prescribed for appropriate hemophilia disorder (Hemophilia A vs. B) or other appropriate bleeding disorder, if applicable AND
3. Confirmed the agent and dosing is for appropriate indication (acute bleeding vs. prophylaxis dosing).

Antihistamines (oral, sedating): diphenhydramine (Benadryl®), hydroxyzine (Atarax® Vistaril®), cyproheptadine (Periactin®)

1. Formulary - MRC use only, restricted to dialysis only.
2. Patients taking antipsychotic medication with extrapyramidal symptoms not responsive to benztropine and trihexyphenidyl (diphenhydramine and hydroxyzine only).
3. Excessive salivation with clozapine (diphenhydramine and hydroxyzine only).
4. Chronic idiopathic urticaria (consider other formulary H2 blockers such as doxepin).
5. Chronic pruritus-associated dialysis (diphenhydramine and hydroxyzine only).
6. Non-formulary use approved via DIRECTLY OBSERVED THERAPY ONLY for cyproheptadine.
7. **Urticaria:** Classified according to etiology or precipitating factor. All potential precipitating factors have been considered and controlled.
8. **Urticaria:** IgE levels and/or absolute eosinophil count in conditions where this is typically seen.
9. **Urticaria:** Documented failure (ensuring compliance) of steroid pulse therapy (i.e. prednisone 30mg daily for 1 to 3 weeks). **Be aware of any contraindication to steroid use (i.e. bipolar disorder)**.

Antihistamines (oral, non-sedating): cetirizine (Zyrtec®), fexofenadine (Allegra®), loratadine (Claritin®)

1. Failure of two antihistamines obtained through the commissary within the last 90 days.
2. Patient is indigent AND treatment is medically necessary. Orders are limited to 30 days in duration when approved based on indigent status alone. If renewed, indigent status will be reassessed
3. Ordered or recommended by an ENT specialist.

Apremilast (Otezla®)

Use for psoriasis must be in consultation with a dermatologist. Use for psoriatic arthritis:

1. Failure of methotrexate/prednisone, gold, or azathioprine.
2. Request must include a rheumatology consult report.

Aripiprazole lauroxil ER (Aristada INITIO®)

1. Patient is being initiated on long-acting aripiprazole and is unable to take lead-in oral aripiprazole.

Artificial tears solution and ointment: various OTC formulations

1. Initiated by an optometrist or ophthalmologist with ongoing evaluation AND
2. Failure of commissary alternatives OR patient is indigent AND treatment is medically necessary. Orders are limited to 30 days.

Ascorbic acid: vitamin C

1. Concomitant administration with an imidazole antifungal agent to improve bioavailability by increasing stomach acidity.

Asenapine (Saphris®)

1. Request is in accordance with the Schizophrenia and/or Bipolar Clinical Guidance documents or justification as to why prescribing has diverged from recommendations is documented in request.
2. Patient has documented noncompliance per eMAR.
3. In noncompliant patients, justification for why a formulary Long Acting Injectable (LAI) antipsychotic cannot be used is documented in the request.

4. In noncompliant patients, documentation as to why more cost effective oral options for noncompliant patients cannot be used or why use of asenapine is preferred to each more cost effective agent is documented in the request. Cost comparison must be determined at time of submission for the following alternatives: aripiprazole ODT/solution, risperidone ODT/solution, olanzapine OTD, haloperidol elixir, and fluphenazine elixir/concentrate).

Atogepant (Qulipta) – See Calcitonin gene-related peptide (CGRP) antagonists

Azithromycin, Oral

1. Acne: Treatment of moderate or severe acne.
2. Acne: Failure of at least 2 topical agents.

Baclofen – See Muscle relaxants

Baricitnib (Olumiant ®)

1. Patient has been diagnosed with moderate to severe atopic dermatitis by a dermatologist AND
2. Self-management with fragrance-free moisturizers has been tried for at least 6 continuous weeks without symptom improvement AND
3. Patient has a contraindication to, intolerability to, or have failed at least 12 weeks of treatment with at least ONE medication in EACH of the following categories: AND
    a. High potency/class 1 topical corticosteroids
    b. Topical calcineurin inhibitor
4. Patients has an allergy, documented intolerance, or failure with an adequate trial of dupilumab or tralokinumab.
5. If all other criteria are met, the least costly biologic for the requested indication at the time of request will be approved.

Benzoyl peroxide (wash/soap)

1. Chronic cystic scarring acne and/or causing secondary bacterial infections OR
2. Patient is indigent AND treatment is medically necessary. Orders are limited to 30 days in duration when approved on the basis of indigent status alone. If renewed, indigent status will be reassessed.

Becaplermin (Regranex®)

1. Patients should have a recent glycosylated hemoglobin (hemoglobin A1C or HbA1C) less than 8. If not, aggressive control of their diabetes should be attempted.
2. Patients should be non-smoking or enrolled in a smoking cessation plan.
3. Stage III or IV (International Association of Enterostomal Therapy for staging chronic wounds) lower extremity diabetic ulcers that extend through the dermis into the subcutaneous tissue or beyond.
4. The wound must have an adequate blood supply measured by Oscillometry (at least 2 units), transcutaneous oxygen pressure (TcpO2 >30 mm Hg) or bleeding with debridement.
5. The wound must be free from infection.
6. If present, lower extremity edema should be treated.
7. The patient must have failed standard therapy for at least 2 months (careful/frequent debridement, moist dressing changes and non-weight bearing).

8. The provider must see the patient on a weekly to biweekly basis for debridement and assessment of ulcer response.
9. The provider must recalculate a new amount of becaplermin gel to be applied at every visit.

Benzodiazepines: clonazepam and lorazepam, long-term use (>30 days)

1. Control of severe agitation in psychiatric patients
2. When lack of sleep causes an exacerbation of psychiatric illness
3. Part of a prolonged taper schedule
4. Detoxification for substance abuse
5. Failure of standard modalities for seizure disorders (4th line therapy)
6. Long-term use for terminally ill patients for palliative care (e.g. hospice patients)
7. Adjunct to neuroleptic therapy to stabilize psychosis
8. Second line therapy for anti-mania
9. Psychotic syndromes presenting with catatonia (refer to BOP Schizophrenia Clinical Practice Guideline)
10. Akathisia that is non-responsive to beta blocker at maximum dose or unsuccessful conversion to another antipsychotic agent (refer to BOP Schizophrenia Clinical Practice Guideline)
11. Nausea and vomiting in oncology treatment patients (lorazepam only)

Beta-3 adrenergic agonists: mirabegron (Myrbetriq®) and vibegron (Gemtesa®)

1. Patient has a confirmed diagnosis of overactive bladder (OAB) with symptoms of urge incontinence, urgency, and urinary frequency.
2. Treatment failure with behavioral interventions to include pelvic floor muscle training in women, bladder training, and fluid restriction.
3. Treatment failure of 12-week trial (with compliance) of an anti-muscarinic agent (or a contradiction to these agents).
4. Requested agent is used in combination with another anti-muscarinic agent (unless contraindicated).
5. CrCl > 15 ml/min and not be on hemodialysis

Betamethasone (Beconase®AQ) – See Steroid nasal sprays

Bismuth subsalicylate (Pepto Bismol®)

1. Patient is indigent, treatment is medically necessary, AND has failed OTC Indigent program alternatives. Orders are limited to 30 days in duration.

Bosentan (Tracleer®)

1. Patient is under the care of a specialist for the treatment of pulmonary hypertension AND
2. Patient is prescribed a phosphodiesterase-5 inhibitor, unless contraindicated or not tolerated.
3. Requests for endothelin receptor antagonists will be approved for ambrisentan, unless justification is provided for why this agent cannot be used.

Brexpiprazole (Rexulti®)

1. Medication is being used to treat schizophrenia OR to treat refractory depressive disorder as an augmentation medication to an existing antidepressant.
2. Schizophrenia: Patient had treatment failures with at least 3 other atypical antipsychotics (one of which MUST be aripiprazole unless contraindicated).

3. Refractory Depressive disorder: Patient had treatment failure with at least 3 other antidepressant augmentation strategies (one of which MUST be aripiprazole unless contraindicated)
4. Patient experienced an adverse event with aripiprazole that is not expected to occur with brexpiprazole (Rexulti®)
5. Details related to prior treatment failures (to include all antipsychotics and adjunct treatments for refractory depressive disorder) are documented in the below justification for use comments to include medications, doses, durations, compliance, and adverse drugs reactions (if applicable)
6. Patients who arrived to the BOP on this medication (post initial intake order): The provider has concerns related to potential destabilization if medication discontinued. Specific concerns must be detailed below.

Brimonidine 0.1% and 0.15% ophthalmic solution (Alphagan P®)

1. Documented allergy or sensitivity to brimonidine 0.2% ophthalmic solution.

Brivaracetam (Briviact®)

1. Prescribed for the treatment of partial-onset seizures AND
2. Recommended by a neurologist AND
3. Patient has failed an adequate trial of levetiracetam or has an allergy or intolerance to levetiracetam AND
4. Patient has failed an adequate trial of two or more formulary antiepileptics.

Buprenorphine (Sublocade ®, Brixadi ®)

1. Institution has an active REMS enrollment, and documentation is clearly provided that demonstrates patient meets ANY of the following criteria:
2. Failure to meet treatment goals on sublingual buprenorphine/naloxone despite an appropriate dosage (at least 16 mg daily), evidence of compliance, AND for a duration of at least 3 months. See OUD Modules for guidance on treatment goals.
3. Confirmed diversion with documented clinical follow up to include counseling and assessment for reasons for diversion AND buprenorphine remains the best option.
4. Patient has significant, documented neurological or psychiatric comorbidities which preclude successful administration of formulary options on directly observed therapy (pill line).
5. Transferring custody within 30 days and use of a long-acting injection will more appropriately ensure continuity of care.

Bupropion (Wellbutrin®IR, SR, and XL; Zyban®)

1. Restricted to bipolar depression or ADHD with coexisting mental health disorder.
2. Patient has NO history of diverting bupropion OR seizure disorders.
3. Bupropion is NOT being requested for smoking cessation or for use as a sleep agent.
4. Initiation requests: Only IR formulation will be approved.
5. BIPOLAR DEPRESSION: Maintained on a mood stabilizer and/or antipsychotic.
6. BIPOLAR DEPRESSION: Failed therapy with at least three (3) other formulary antidepressant agents UNLESS documented manic episode precipitated by the addition of an antidepressant.
7. ADHD: Documented failure of psychotherapy targeting coping, organizational, prioritization, and anger management skills for minimum of 6 months. Psychotherapy should continue if bupropion is approved.
8. ADHD: Failure of ADEQUATE trials (compliant > 6 weeks) of ALL medications listed below or justification of why they cannot be utilized (self-reported trials will not be accepted):
    a. Atomoxetine

   b. Atomoxetine plus guanfacine
   c. Atomoxetine plus clonidine
   d. Desipramine
9. ADHD with co-occurring anxiety disorder: failure with an ADEQUATE trial (compliant >6 weeks) of both an SSRI and SNRI.
10. The following are documented in detail within the comments section below or attached to the NFR request. Failure to provide all documentation may result is NFR deferral or denial:
   a. Psychiatric or psychological behavioral function evaluations with dates of BEMR/PDS notes
   b. Evidence (with specific examples) of inability to function in the correctional environment and the goals associated with bupropion initiation
   c. Medication information including initiation/discontinue dates, doses, DOT or KOP status, and compliance rates (as percentages), as well as any adverse reactions with their severity and date of occurrence.

Cabotegravir and rilpivirine intramuscular (IM) extended-release injectable suspension (Cabenuva®)

1. Patient is unable to use oral alternatives.

Calcitonin gene-related peptide (CGRP) antagonists: erenumab-aooe (Aimovig®), eptinezumab-jjmr (Vyepti®), fremanezumab-vfrm (Ajovy®), galcanezumab (Emgality®)

1. Failure of an 8-week trial (at a therapeutic dose) of one agent from each of the following agent/classes: calcium channel blockers, beta blockers (metoprolol and propranolol), SNRIs (venlafaxine), amitriptyline, ARBs/ACE inhibitors and anticonvulsants.

Calcitonin gene-related peptide (CGRP) antagonists (small-molecule): ubrogepant (Ubrelvy®), rimegepant (Nurtec®ODT), atogepant (Qulipta)

1. Failure of or contraindication to formulary serotonin 5-HT1B/1D receptor agonists (“triptans”).

Calcium carbonate (Tums®)

1. Patient is indigent, treatment is medically necessary, AND has failed OTC indigent program alternatives. Orders are limited to 30 days in duration.

Canagliflozin (Invokana®)

1. Preferred agent is empagliflozin (Jardiance®).
2. Not approved for Type 1 DM.

Carbamide peroxide 6.5% ear drops (Debrox®)

1. Patient is indigent AND treatment is medically necessary. Orders are limited to 10 days in duration when approved on the basis of indigent status alone. If renewed, indigent status will be reassessed.

Carbamazepine oral (Tegretol®)

1. Bipolar disorder: Patient failed therapy (or use contraindicated) with lithium, lamotrigine, valproate, and/or second-generation antipsychotics.
2. Pain management: Patient failed therapy (or use contraindicated) with SNRIs and TCAs.

Cariprazine (Vraylar®)

1. Persistent negative symptoms after failing 2 or more antipsychotic agents.
2. Significant metabolic or movement disorders on 2 or more antipsychotic agents.

Certolizumab pegol (Cimzia®)

1. Adalimumab is recommended agent before etanercept and golimumab due to better side effect profile and cost effectiveness.
2. Failure of an adequate trial of maximally dosed/tolerated methotrexate/prednisone or other formulary non-biologic DMARDs.
3. Intolerable side effects of methotrexate where a TNF agent may allow a decrease in methotrexate dose.
4. All new and renewal prescriptions require consultation with an appropriate specialist based on the disease state being treated (for example, dermatologist, gastroenterologist, or rheumatologist). Consult must be uploaded in BEMR.
5. Requests for patients with a TST > or = 5mm or positive IGRA (interferon gamma release assay) test must be accompanied by evidence of LTBI treatment completion (medication used with ingested dose counts). TST or IGRA must be repeated yearly.
6. Initial requests must include HBV/HCV serology for prior evidence of hepatitis infection.
7. For chronic plaque psoriasis:
    a. Request includes documented percent of affected BSA % AND
    b. Patient has failed of an adequate trial of a clinically indicated formulary non-biologic agent AND
    c. ≥ 10% BSA is affected (Severe CPP) OR
    d. At least ≥ 5% of BSA (Moderate CPP) AND crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
    e. NFR renewals must include documentation of improved symptoms (% BSA impacted)

Patients with mild CPP may be managed with formulary topical treatments.

Cetirizine (Zyrtec®) – See Antihistamines (oral, non-sedating)

Cladribine (Mavenclad®)

1. Prescribed by, or in consultation with, a neurologist or other appropriate specialist for the treated disease state.
2. Confirmed diagnosis of relapsing forms of multiple sclerosis – including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
3. Failure (or use contraindicated) of formulary options or justification why formulary options cannot be used.

Clindamycin, oral

1. Acne: Treatment of moderate or severe acne.
2. Acne: Failure of at least 2 topical agents.

Clobetasol topical solution and foam

1. Patient has failed clobetasol cream and ointment formulation AND
2. Patient has failed tacrolimus and/or calcipotriene topical agents.

Clobazam (Onfi®)

1. Prescribed for the treatment of Lennox-Gastaut syndrome AND
2. Recommended by a neurologist AND
3. Patient has failed an adequate trial of two or more formulary agents for Lennox-Gastaut syndrome.

Clonazepam (long-term use) – See Benzodiazepines

Clonidine (Catapres®)

1. Dose taper over 2 to 4 days for arriving patients taking greater than 1 mg per day. Refer to clonidine withdrawal guidance, particularly for patients on concomitant beta blocker therapy. Non-formulary request may be submitted after taper initiated.
2. Use in clozapine induced hypersalivation (CIH) after failure or contraindication to benztropine, amitriptyline, and alpha blocker. **NOTE:** Including combination therapy with benztropine and an alpha blocker for 12 weeks.
3. Use in Tourette's syndrome.
4. Not to be used in hypertensive urgencies/ emergencies. See Hypertensive clinical practice guidelines and 2006 National P&T Minutes, page 103.
5. ADHD: Patient has documented diagnosis of ADHD.
6. ADHD: Patient has documented failure of (at a therapeutic dose and for a therapeutic duration) preferred agents (atomoxetine and guanfacine) or justification as to why alternatives cannot be utilized is explained in the comments below.
7. Patient does not have conditions that would predispose them to the negative cardiac outcomes that have been associated with clonidine (e.g., hypotension, heart block, bradycardia, etc.)
8. Patient's renal function is deemed acceptable for use.

Clonidine Discontinuation Guidance

Discontinuation of most any antihypertensive agent can lead to a corresponding withdrawal syndrome. However, this syndrome is most commonly seen with clonidine, beta-blockers, methyldopa, and guanabenz. The withdrawal syndrome is thought to be caused by sympathetic over activity and includes nervousness, tachycardia, headache, agitation, and nausea.

This is usually seen within 36 to 72 hours after cessation of therapy. In rare instances, a rapid increase in blood pressure to pre-treatment levels or above can be seen that could potentially lead to myocardial ischemia. Again, this is rare, especially when patients are not taking above the standard therapeutic doses of these agents. It also appears to occur more often when multiple medications are being withdrawn at the same time.

Abrupt discontinuation of clonidine, in particular those taking greater than 1 mg daily, may result in nervousness, agitation, restlessness, anxiety, insomnia, headache, sweating, palpitation, increased heart rate, tremor, hiccups, muscle pain, increased salivation, stomach pain, nausea and flushing. This may be due in part to the fact that clonidine has been shown to act upon opiate receptors. These effects generally appear within two to three hours after the first missed dose.

Blood pressure may increase in four to eight hours after the first missed dose of clonidine and is associated with a rise in catecholamine plasma concentrations. This potential may be exacerbated after administration of higher doses or continued concurrent therapy with a beta-blocker.

Severe blood pressure increases after clonidine discontinuation can be treated with the reinstitution of clonidine therapy followed by a short, gradual taper over two to four days; IV phentolamine +/- propranolol (propranolol should never be utilized alone as it may further elevate the BP); or utilization of a vasodilator such as hydralazine or diazoxide.

If a patient is taking clonidine concurrently with a beta-blocker, it is best to gradually withdraw the beta blocker, then withdraw the clonidine over two to four days. The beta-blocker can then be reinstituted after clonidine has been successfully withdrawn. Concurrent beta-blocker therapy may exacerbate an increase in blood pressure upon clonidine withdrawal.

Appropriate follow-up to including adjustment of medication management of all patients is essential during this process.

Coal tar shampoo/gel/solution

1. Documented failure of OTC commissary selenium or coal tar shampoo OR
2. Patient is indigent, treatment medically necessary, AND has failed OTC Indigent Program alternatives (ex: selenium 1% shampoo). Orders are limited to 30 days in duration when approved on the basis of indigent status alone. If renewed, indigent status will be reassessed.
3. For Psoriasis: lesions interfere with function.
4. For Psoriasis: Psoriasis affects >10% of BSA (refer patients to commissary for mild psoriasis) OR crucial body areas (hands, feet, face, etc.).

Copper Intra-Uterine Device (Paragard®)

1. Request is for continuity of care for patient who entered BOP custody with this IUD already in place. (Patients entering the BOP with these devices in place must have the product name and expiration/replacement date documented in the health record. These devices may be removed upon expiration or sooner at the patient's request).
2. Unless this patient's case meets criteria #1, this request will be disapproved. The Patient Care program statement prohibits initiation of IUDs for birth control for inmates housed in BOP facilities.

Cyclobenzaprine (Flexeril®) – See Muscle relaxants

Cyclosporine ophthalmic emulsion 0.05% (Restasis®)

1. Diagnosis of Sjogren's Syndrome.
2. Diagnosis of Rheumatoid Arthritis.
3. Failed appropriate duration of carboxymethylcellulose (Celluvisc®) containing ocular lubricants via approved non- formulary request.

Cyproheptadine (Periactin®) – See Antihistamines

Dapagliflozin (Farxiga®)

1. Preferred agent is empagliflozin (Jardiance®).
2. Not approved for Type 1 DM.

Darbopoetin alfa (Aranesp®) – See Erythropoesis-stimulating agents (ESAs)

Denture Adhesives (Fixodent®etc.)

1. Patient is indigent. Orders are limited to 30 days in duration when approved on the basis of indigent status alone. If renewed, indigent status will be reassessed.
2. Patient has no commissary access (confirmed through TRUFACTS).
3. Patient has a denture.

Dibucaine ointment – See Hemorrhoidal cream/ointment

Dicyclomine (Bentyl®)

1. Clinical diagnosis of IBS AND
2. Three months of fiber (tablets) therapy without relief of symptoms AND
3. Age-appropriate screening for colorectal cancer with three negative Fecal Occult Blood Tests (or one negative Fecal Immunochemical Test) documented in BEMR, AND
4. At least six months of chronic diarrhea symptoms AND
5. Absence of constipation and/or positive Fecal Occult Blood Test. Any new or renewal orders for dicyclomine must meet the criteria to be dispensed.

Dietary/herbal supplements

These agents are not FDA approved and will not be approved.

Difluprednate (Durezol®)

1. Difluprednate has less ocular effect than prednisolone. Patient case must have potential or actual increase in intraocular pressure for non-formulary request approval.

Dipeptidyl peptidase-4 (DPP-4) inhibitors: linagliptin (Tradjenta®), alogliptin (Nesina®), saxagliptin (Onglyza®), sitagliptin (Januvia®)

1. Patient has type 2 diabetes.
2. Not to be used in combination with GLP-1 agonists.
3. Frequent hypoglycemia on sulfonylurea.
4. Failed maximum tolerated dose of metformin or documented contraindication to metformin.
5. A1C goal not met on therapeutic doses of formulary agents.
6. A1C <9% (if A1C is ≥9%, then insulin therapy is indicated instead of this agent).
7. Criteria 1 through 6 must be met for approval.

Diphenhydramine (Benadryl®) – See Antihistamines (oral, sedating)

Diroximel fumarate (Vumerity®)

1. Prescribed by, or in consultation with, a neurologist or other appropriate specialist for the treated disease state.
2. Confirmed diagnosis of relapsing forms of multiple sclerosis – including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
3. Failure (or use contraindicated) of formulary options or justification why formulary options cannot be used.

Docusate sodium

1. Patient is indigent, treatment is medically necessary, AND has failed OTC Indigent program alternatives . Orders are limited to 30 days in duration.

Doxycyline, oral

1. Acne: Treatment of moderate or severe acne.
2. Acne: Failure of at least 2 topical agents.

Dulaglutide (Trulicity®)

1. Preferred agent: semaglutide (Ozempic®) injection.
2. Not approved for Type 1 DM.

Dupilumab injection (Dupixent®)

1. ASTHMA
    a. The patient has persistently uncontrolled asthma after a reasonable trial of high-dose ICS/LABA and antileukotriene (e.g., montelukast).
    b. The patient completed observed inhaler technique with correction as needed.
    c. The patient has been tested for responsiveness to glucocorticoids AND **Injection of long-acting GC (e.g., IM triamcinolone 120 mg); post 2-week assessment achieving improvement in FEV1 and reduced rescue inhaler use**
    d. The patient has a blood eosinophil level ≥ 150 cells/µl or FeNO ≥ 25 ppb.
    e. The has patient failed omalizumab (Xolair®) (or has a contraindication).
    f. Dupilumab been recommended by a specialist. (Please upload in Document Manager.)
2. ATOPIC DERMATITIS
    a. Patient has been diagnosed with moderate to severe atopic dermatitis by a dermatologist AND
    b. Self-management with fragrance-free moisturizers has been tried for at least 6 continuous weeks without symptom improvement AND
    c. Patient has a contraindication to, intolerability to, or have failed at least 12 weeks of treatment with at least ONE medication in EACH of the following categories:
    d. High potency/class 1 topical corticosteroids
    e. Topical calcineurin inhibitor
    f. If all other criteria are met, the least costly biologic for the requested indication at the time of request will be approved.

Dutasteride (Avodart®)

1. Second line agent for BPH, after failure of alpha blocker.
2. American Urological Association criteria (including symptom score, digital rectal exam, PSA test, urine outflow record) are submitted.
3. Finasteride is the 5-alpha-reductase Inhibitor of choice**

Emtricitabine / tenofovir alafenamide (Descovy®)

1. Does the patient have a CrCl < 60ml/min? (Yes/No)
2. Does the patient have osteoporosis or is at high risk for osteoporosis? (Yes/No)

Enfuvirtide (Fuzeon®) – See HIV medication

Epoprostenol (Flolan®, Veletri®)

1. Patient is under the care of a specialist for the treatment of pulmonary hypertension.

Eptinezumab-jjmr (Vyepti®) – See Calcitonin gene-related peptide (CGRP) antagonists

Erenumab-aooe (Amovig®) – See Calcitonin gene-related peptide (CGRP) antagonists

Ertugliflozen (Steglatro®)

1. Preferred agent is empagliflozin (Jardiance®).
2. Not approved for Type 1 DM.

Erythropoesis-stimulating agents (ESAs): epoetin alfa (Epogen®, Procrit®), epoetin alfa-epbx (Retacrit®) (HCV only), darbopoetin alfa (Aranesp®) (HCV only)

1. Epoetin alfa-epbx (Retacrit®) is the preferred formulary alternative.
2. For Hepatitis C: Patient receiving hepatitis C therapy; AND
3. For Hepatitis C: Patient is one of the following:
    a. Cirrhotic;
    b. Pre or post-liver transplant
    c. HIV/HCV co-infected;
    d. Receiving HIV triple therapy; AND
4. For Hepatitis C: Patient underwent evaluation for other causes of anemia (e.g. bleeding, nutritional deficiency) and has been treated appropriately; AND
5. For Hepatitis C: Patient develops anemia defined as Hgb < 10 g/dL (or as clinically indicated for significant anemia-related signs and symptoms) and persists for at least two weeks after reducing the ribavirin dose to 600 mg/day; AND
6. For Hepatitis C: Patient does not have exclusion criteria: Uncontrolled hypertension or risk for thrombosis.

Esketamine nasal solution (Spravato®)

1. Patient has documented diagnosis of treatment-resistant depression OR major depressive disorder (MDD) with acute suicidal ideation or behavior.
2. Provider, pharmacy, and patient are enrolled in Spravato risk evaluation mitigation strategy (REMS) program.
3. Provide appropriate patient monitoring according to manufacturer recommendations.
4. Patient does not have a history of aneurysmal vascular disease, arteriovenous malformation, or intracerebral hemorrhage.
5. Patient has documented failure (at a therapeutic dose and for a therapeutic duration) to several formulary agents from multiple classes to include augmentation strategies for depression or justification as to why alternatives cannot be utilized is explained in the comments above.
6. Appropriate monitoring related to blood pressure will be completed (before and after treatment) to reduce risk of increase in blood pressure or intracranial pressure.
7. Medication should be administered as Directly Observed Therapy ONLY due to potential of abuse and misuse.

Etanercept (Enbrel®)

1. Adalimumab is recommended agent before etanercept and golimumab due to better side effect profile and cost effectiveness.
2. Failure of an adequate trial of maximally dosed/tolerated methotrexate/prednisone or other formulary non-biologic DMARDs.
3. Intolerable side effects of methotrexate where a TNF agent may allow a decrease in methotrexate dose.
4. All new and renewal prescriptions require consultation with an appropriate specialist based on the disease state being treated (for example, dermatologist, gastroenterologist, or rheumatologist). Consult must be uploaded in BEMR.
5. Requests for patients with a TST > or = 5mm or positive IGRA (interferon gamma release assay) test must be accompanied by evidence of LTBI treatment completion (medication used with ingested dose counts). TST or IGRA must be repeated yearly.
6. Initial requests must include HBV/HCV serology for prior evidence of hepatitis infection.
7. For chronic plaque psoriasis:
    a. Request includes documented percent of affected BSA % AND
    b. Patient has failed of an adequate trial of a clinically indicated formulary non-biologic agent AND
    c. ≥ 10% BSA is affected (Severe CPP) OR
    d. At least ≥ 5% of BSA (Moderate CPP) AND crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
    e. NFR renewals must include documentation of improved symptoms (% BSA impacted)
    f. Patients with mild CPP may be managed with formulary topical treatments.

Ethosuximide (Zarontin®)

Approval of any non-formulary antiepileptic medications will be considered on an individual basis. When requesting approval please provide information necessary for evaluation of the request. This will include:

1. Previous medications, doses, and documented compliance; blood levels when appropriate.
2. EEG or clinical evidence of failure to achieve seizure-free state.
3. Documented adverse effects of formulary medications.
4. Results of any neurologic consultations.
5. Please be aware that many of the antiepileptic agents have potentially life- threatening side effects under certain conditions, or in some individuals. The prescriber should take special care:
    a. To assess and follow the patient for potential adverse side-effects.
    b. Be aware of any potential drug-drug interactions.
    c. Adjust dose no more quickly than recommended by the manufacturer.
    d. Monitor compliance.

Etravirine (Intelence®) – See HIV medication/treatments

Exenatide ER (Bydureon®)

1. Preferred agent: semaglutide (Ozempic®)
2. Not approved for Type 1 DM.

Ezetimibe (Zetia®)

1. Ezetimibe 10 mg daily can be considered on a non-formulary basis for those high risk and very high risk patients not meeting their LDL-C goal and considered for PCSK9 inhibitor therapy on "intensive" statin therapy or highest tolerable statin dose.
2. Patient is "intolerant" to statins. Trials on multiple formulary statins to be considered before determining a patient is "intolerant" to all statins and/or when considering highest tolerable statin dose.

Febuxostat (Uloric®)

1. Inadequate response to allopurinol 600mg/day (300mg/day in patients with renal impairment).
2. Inadequate response to maximally tolerated allopurinol dose + maximally tolerated uricosuric agent: probenecid, fenofibrate, or losartan.
3. All non-essential pharmaceuticals that induce hyperuricemia have been discontinued (e.g., thiazides/loop diuretics, low-dose aspirin, beta-blocker, niacin).
4. Patient is intolerant to allopurinol.
5. Treatment with allopurinol is not advisable (HLA-B*5801-positive) or contraindicated.

Felbamate (Felbatol®)

1. Previous medications, doses, and documented compliance; blood levels when appropriate.
2. EEG or clinical evidence of failure to achieve seizure-free state.
3. Documented adverse effects of formulary medications.
4. Results of any neurologic consultations.
5. Please be aware that many of the antiepileptic agents have potentially life- threatening side effects under certain conditions, or in some individuals. The prescriber should take special care:
    a. To assess and follow the patient for potential adverse side-effects.
    b. Be aware of any potential drug-drug interactions.
    c. Adjust dose no more quickly than recommended by the manufacturer.
    d. Monitor compliance.

Fexofenadine (Allergra®) – See Antihistamines (oral, non-sedating)

Fidaxomicin (Dificid®)

1. Use in patients > 65 years old who are immunocompromised
2. Use in severe *C. difficile* infection (WBC count > 15,000 cells/mcL; sCr >/= 1.5 mg/dL).

Filgrastim (Neupogen®), filgrastim-sndz (Zarxio®), filgrastim-aafi (Nivestym®) – See Granulocyte colony-stimulating factors (G-CSFs)

Finerenone (Kerendia®)

1. Patient has type 2 diabetes mellitus with associated chronic kidney disease, AND
2. Persistently elevated urinary albumin excretion (urine albumin-to-creatinine ratio >=30mg/g), AND
3. Patient is on optimized preferred therapy (blood pressure control including ACEI-inhibitor or ARB, glycemic control, and kidney-protective therapy with SGLT-inhibitor)

Fluconazole oral (Diflucan ®)

1. Diabetic or circulatory disorders evidenced by absence of pedal pulses and/or extremity hair loss due to poor circulation, or abnormal monofilament exam demonstrating loss of sensation, OR
2. Fungal nail infection (onychomycosis) with presence of secondary bacterial co-infection, OR
3. Patient is immunocompromised.
4. Onychomycosis requests meeting criteria will be approved for terbinafine (Lamisil®) 250 mg daily for 6 to 12 weeks for fingernails or toenails respectively.
5. Tinea/Superficial Mycosis: Failure of at least 4-weeks trial of topical antifungals.

Fluoroquinolones: Ciprofloxacin (Cipro®) and Levofloxacin (Levaquin®)

1. For UTI
    a. UTI is considered complicated (e.g., obstruction, reflux, azotemia, transplant) or catheter associated.
    b. For acute cystitis, first-line therapy with sulfamethoxazole/trimethoprim and nitrofurantoin have failed or are contraindicated.
2. For pneumonia
    a. Patient has risk factors for pseudomonas or MRSA. Comorbidities present (chronic heart, lung, liver, or renal disease; diabetes; alcohol use disorder; neoplastic disease, asplenia).
    b. Antibiotic use within the past 3 months.
3. For COPD exacerbation
    a. Patient has risk factors for poor outcome (age greater than 65 years, FEV1 < 50%, recent hospitalization or antibiotic use, history of pseudomonas infection, more than 1 exacerbation in past 12 months).
    b. Patient has contraindications to azithromycin or cefdinir
4. For acute sinusitis
    a. Patient has clinical failure after 3 days of empiric antibiotic treatment (persistent sinus pain, nasal congestion, purulent nasal discharge, and/or fever despite recommended therapy).
5. For otitis media
    a. Patient has had antibiotics in the previous month AND a has documented penicillin allergy.
    b. Patient has clinical failure after 3 days of empiric antibiotic treatment (no change in ear pain, fever, bulging tympanic membrane, or otorrhea) AND has a documented penicillin allergy.
6. For *H. pylori*
    a. Patient has failed both first-line treatment options (per current guidelines).
    b. Prescribed along with amoxicillin and omeprazole for 14 days at appropriate doses.
7. For biopsy/procedure
    a. Please indicate if use for biopsy/procedure, if recommended by specialist, and date of procedure (if known).
8. For use based on available culture and sensitivity results
    a. Susceptible to fluoroquinolone and intermediate or fully resistant to all other formulary options.

Fluticasone nasal spray (Flonase®) – See Steroid nasal sprays

Fluticasone oral inhaler (Flovent®)

1. Must fail two other inhaled corticosteroids with demonstrated compliance.

Fluticasone/salmeterol (Advair®, AirDuo®, Wixela®) – See Long-acting beta agonists (LABA) / inhaled corticosteroids (ICS)

Fluticasone/vilanterol (Breo®) – See Long-acting beta agonists (LABA) / inhaled corticosteroids (ICS)

Fremanezumab-vfrm (Ajovy®) – See Calcitonin gene-related peptide (CGRP) antagonists

Galcanezumab (Emgality®) – See Calcitonin gene-related peptide (CGRP) antagonists

Gemfibrozil (Lopid®)

1. Diagnosis of severe hypertriglyceridemia (triglycerides ≥500 mg/dL) AND failure of fenofibrate used for at least 6 months.

Golimumab (Simponi®)

1. Adalimumab is recommended agent before etanercept and golimumab due to better side effect profile and cost effectiveness.
2. Failure of an adequate trial of maximally dosed/tolerated methotrexate/prednisone or other formulary non-biologic DMARDs.
3. Intolerable side effects of methotrexate where a TNF agent may allow a decrease in methotrexate dose.
4. All new and renewal prescriptions require consultation with an appropriate specialist based on the disease state being treated (for example, dermatologist, gastroenterologist, or rheumatologist). Consult must be uploaded in BEMR.
5. Requests for patients with a TST > or = 5mm or positive IGRA (interferon gamma release assay) test must be accompanied by evidence of LTBI treatment completion (medication used with ingested dose counts). TST or IGRA must be repeated yearly.
6. Initial requests must include HBV/HCV serology for prior evidence of hepatitis infection.
7. For chronic plaque psoriasis:
    a. Request includes documented percent of affected BSA % AND
    b. Patient has failed of an adequate trial of a clinically indicated formulary non-biologic agent AND
    c. ≥ 10% BSA is affected (Severe CPP) OR
    d. At least ≥ 5% of BSA (Moderate CPP) AND crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
    e. NFR renewals must include documentation of improved symptoms (% BSA impacted)
    f. Patients with mild CPP may be managed with formulary topical treatments.

Granulocyte colony-stimulating factors (G-CSFs): filgrastim (Neupogen®and biosimilars), pegfilgrastim (Neulasta®and biosimilars)

1. Pegfilgrastim-bmez (Ziextenzo®) is the preferred formulary agent.
2. Adjunctive therapy for cancer chemotherapy.
    a. Chemotherapy primary prophylaxis for “dose dense” treatment regimen.
    b. Chemotherapy primary prophylaxis for treatment regimen with 20% or higher risk of febrile neutropenia.
    c. Chemotherapy primary prophylaxis for patient older than 65, poor performance status, combined chemo- radiotherapy, poor nutritional status, advanced cancer, or other serious comorbidities.
    d. Chemotherapy secondary prophylaxis for patient with history of prior neutropenic complications.

3. All of the following must be true for patient to be eligible for filgrastim treatment of hepatitis C treatment-related neutropenia:
    a. Patient receiving hepatitis C therapy; AND
    b. Patient develops neutropenia defined as either
        i. ANC < 250/mm3; **OR**
        ii. ANC < 500mm3 with one of the following risk factors for developing infection;
            1. Cirrhosis, biopsy proven or clinically evident;
            2. Pre-or post-liver transplant;
            3. HIV/HCV co-infection
            4. Receiving HCV triple therapy; **AND**
    c. Patient has failed to respond (i.e. neutropenia persists) despite at least two weeks of peginterferon dose reduction

Griseofulvin

1. Diabetic or circulatory disorders evidenced by absence of pedal pulses and/or extremity hair loss due to poor circulation, or abnormal monofilament exam demonstrating loss of sensation, OR
2. Fungal nail infection (onychomycosis) with presence of secondary bacterial co-infection, OR
3. Patient is immunocompromised.
4. Onychomycosis requests meeting criteria will be approved for terbinafine (Lamisil®) 250 mg daily for 6 to 12 weeks for fingernails or toenails respectively.

Hemorrhoidal cream/ointment: phenylephrine (Preparation H®), hydrocortisone (Anusol®), dibucaine

1. Pending hemorrhoid surgery or 30 days (or less) post-hemorrhoid surgery OR
2. Patient is indigent AND treatment is medically necessary. Orders are limited to 30 days in duration when approved on the basis of indigent status alone. If renewed, indigent status will be reassessed.

Hepatitis C treatment algorithm

1. "Medical HOLD" will be placed on patient once hepatitis C treatment therapy is initiated.

HIV medications: etravirine (Intelence®), maraviroc (Selzentry®), tipranavir (Aptivus®), enfuvirtide (Fuzeon®)

1. Regimen has been established in consultation with Regional HIV Consultant Pharmacist, expert consultation service or Regional Medical Director.

Hyaluronic acids: hylan G-F 20 (Synvisc®), sodium hyaluronate (Hyalgan®)

1. Osteoarthritis of the knee(s) (American College of Rheumatology criteria) confirmed by history, exam, and x-ray.
2. Documented inadequate control of pain or intolerance to adequate trial of acetaminophen (4 grams/day), NSAIDs, and other non-narcotic or narcotic analgesics.
3. Inadequate response to intra articular corticosteroid injections.
4. Inadequate response to bracing and use of canes or crutches.
5. Inadequate response to measures such as weight loss and physical therapy.
6. Surgery is not an option due to concurrent medical conditions that preclude the patient as candidate for surgery. These agents may also be considered as a bridging option before resorting to surgery.

Hydrocortisone cream, ointment (OTC)

1. Patient is indigent and has failed OTC Indigent Program alternatives (ex: Hydrocortisone 0.5% cream) and treatment is medically necessary. Orders are limited to 30 days in duration when approved on the basis of indigent status alone. If renewed, indigent status will be reassessed.
2. For Psoriasis: lesions interfere with function
3. For Psoriasis: Psoriasis affects >10% of BSA (refer patients to commissary for mild psoriasis) OR crucial body areas (hands, feet, face etc.)

Hydroxyzine (Atarax® Vistaril®) – See Antihistamines (oral, sedating)

Iloprost (Aurlmyn® Ventavis®)

1. Patient is under the care of a specialist for the treatment of pulmonary hypertension.

Infliximab (Remicade®)

1. Infliximab abda (Renflexis®) is the preferred infliximab agent over both infliximab (Remicade®) and infliximab dyyb (Inflectra®).

Infliximab-abda (Renflexis®), infliximab-dyyb (Inflectra®)

1. Adalimumab is recommended agent before etanercept and golimumab due to better side effect profile and cost effectiveness.
2. Failure of an adequate trial of maximally dosed/tolerated methotrexate/prednisone or other formulary non-biologic DMARDs.
3. Intolerable side effects of methotrexate where a TNF agent may allow a decrease in methotrexate dose.
4. All new and renewal prescriptions require consultation with an appropriate specialist based on the disease state being treated (for example, dermatologist, gastroenterologist, or rheumatologist). Consult must be uploaded in BEMR.
5. Requests for patients with a TST > or = 5mm or positive IGRA (interferon gamma release assay) test must be accompanied by evidence of LTBI treatment completion (medication used with ingested dose counts). TST or IGRA must be repeated yearly.
6. Initial requests must include HBV/HCV serology for prior evidence of hepatitis infection.
7. For chronic plaque psoriasis:
    a. Request includes documented percent of affected BSA % AND
    b. Patient has failed of an adequate trial of a clinically indicated formulary non-biologic agent AND
    c. ≥ 10% BSA is affected (Severe CPP) OR
    d. At least ≥ 5% of BSA (Moderate CPP) AND crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
    e. NFR renewals must include documentation of improved symptoms (% BSA impacted)
    f. Patients with mild CPP may be managed with formulary topical treatments.

Insulin detemir, long-acting insulin (Levemir®)

1. Failure or contraindication to insulin glargine-yfgn (Semglee®).
2. Recurrent episodes of symptomatic hypoglycemia despite multiple attempts with various insulin dosing regimens. Non-formulary request must include documentation of blood glucose values in the hypoglycemic range (i.e. MARs), and the insulin regimens used. **OR;**

3. Failure to achieve target HbA1C goals despite compliance with an intensive insulin regimen (3 to 4 injections / day) using NPH and regular. **NOTE:** The evening dose of NPH should be administered as close to bedtime as staffing and institution procedures permit.) Non-formulary request must include the insulin regimens used, an assessment of compliance (i.e. MARs) and a recent HbA1C result with date.

Insulin aspart / insulin lispro, rapid-acting insulin (Novolog®Humalog®)

NOTE: Generally speaking, insulin lispro and insulin aspart are too short-acting to be used safely in most correctional environments.

1. Unable to achieve glycemic control targets with the use of regular insulin, despite multiple attempts with various insulin dosing regimens.
2. Non-formulary request must include the insulin regimens that have been tried and found ineffective, including times of administration.
3. Self-monitoring of blood glucose or immediate access to blood glucose monitoring at all times.
4. Ability to eat a meal immediately (within 15 minutes) after injecting rapid- acting insulin.
5. Patients receiving highly intensive insulin therapy such as q.i.d. administration, including those who would otherwise be candidates for insulin pump therapy.
6. Will be used at Medical Centers only - is not an acceptable transfer medication.

Interferon beta-1a (Avonex®, Rebif®)

1. Prescribed by, or in consultation with, a neurologist or other appropriate specialist for the treated disease state.
2. Confirmed diagnosis of relapsing forms of multiple sclerosis – including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
3. Failure (or use contraindicated) of formulary options or justification why formulary options cannot be used.

Interferon beta-1b (Betaseron®, Extavia®)

1. Prescribed by, or in consultation with, a neurologist or other appropriate specialist for the treated disease state.
2. Confirmed diagnosis of relapsing forms of multiple sclerosis – including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
3. Failure (or use contraindicated) of formulary options or justification why formulary options cannot be used.

Ipratropium bromide HFA (Atrovent®HFA)

1. Patient is unable to tolerate a short-acting beta agonist (e.g., albuterol).

Isotretinoin (Accutane®)

1. iPLEDGE® enrollment and requirements located at https://www.ipledgeprogram.com Proof of enrollment must be submitted with non-formulary request.
2. Central Office Physician or Regional Medical Director (RMD) have been consulted. This will occur prior to the enrollment of the physician and patient as well as enrollment and fee payment of the institution pharmacy into the iPLEDGE program.

Itraconazole oral (Sporanox®)

1. Diabetic or circulatory disorders evidenced by absence of pedal pulses and/or extremity hair loss due to poor circulation, or abnormal monofilament exam demonstrating loss of sensation, OR
2. Fungal nail infection (onychomycosis) with presence of secondary bacterial co-infection, OR
3. Patient is immunocompromised.
4. Onychomycosis requests meeting criteria will be approved for terbinafine (Lamisil®) 250 mg daily for 6 to 12 weeks for fingernails or toenails respectively.

Ketoconazole oral

1. Diabetic or circulatory disorders evidenced by absence of pedal pulses and/or extremity hair loss due to poor circulation, or abnormal monofilament exam demonstrating loss of sensation, OR
2. Fungal nail infection (onychomycosis) with presence of secondary bacterial co-infection, OR
3. Patient is immunocompromised.
4. Onychomycosis requests meeting criteria will be approved for terbinafine (Lamisil®) 250 mg daily for 6 to 12 weeks for fingernails or toenails respectively.

Ketoconazole shampoo (Nizoral®)

1. Documented failure of OTC commissary selenium sulfide, coal tar shampoo, clotrimazole, AND miconazole OR
2. Patient is indigent, treatment medically necessary AND has failed OTC Indigent Program alternatives (ex: selenium 1% shampoo). Orders are limited to 30 days in duration when approved on the basis of indigent status alone. If renewed, indigent status will be reassessed.

Lacosamide (Vimpat®)

1. Prescribed for the treatment of focal seizures or generalized seizures AND
2. Recommended by a neurologist AND
3. Patient has failed adequate trial of two or more formulary antiepileptics.

Lasmiditan succinate (Reyvow®)

1. Failure of formulary serotonin 5-HT1B/1D receptor agonists (“triptans”).

Lebrikizumab-lbkz (Epglyss®)

1. ATOPIC DERMATITIS
    a. Patient has been diagnosed with moderate to severe atopic dermatitis by a dermatologist AND
    b. Self-management with fragrance-free moisturizers has been tried for at least 6 continuous weeks without symptom improvement AND
    c. Patient has a contraindication to, intolerability to, or have failed at least 12 weeks of treatment with at least ONE medication in EACH of the following categories: AND
        i. High potency/class 1 topical corticosteroids
        ii. Topical calcineurin inhibitor
    d. Patients has an allergy, documented intolerance, or failure with an adequate trial of dupilumab or tralokinumab.
    e. If all other criteria are met, the least costly biologic for the requested indication at the time of request will be approved.

Lecanemab (Leqembi®)

1. Failure of a cholinesterase inhibitor.

Levonorgestrel intrauterine device (Mirena®, Liletta®, Skyla®, Kyleena®)

1. Request is for continuity of care for patient who entered BOP custody with this IUD already in place. (Patients entering the BOP with these devices in place must have the product name and expiration/replacement date documented in the health record. These devices may be removed upon expiration or sooner at the patient's request). OR
2. The primary indication for initiating this treatment is for the medically necessary management of the patient's medical condition (example: abnormal uterine bleeding) and not for the indication of contraception alone AND
3. Oral hormonal tablets and depot medroxyprogesterone have been tried and were not effective, were not tolerated, or are contraindicated for the patient AND
4. The patient's future reproductive plan aligns with the years-long contraception provided by the IUD
5. Levonorgestrel 19.5mg and 13.5mg IUD are indicated for contraception only and are not approved for initiation in the BOP.
6. If above criteria are met, request will be approved for the most cost-effective IUD at time of request.

Levonorgestrel oral (Plan B One-Step®)

1. Administered as soon as possible, within 72 hours of having unprotected sex.
2. Contact the regional chief pharmacist or regional medical director to ensure timely review. Non-Formulary Drug Requests for emergency contraception will be processed and expedited through Central Office.

Linaclotide (Linzess®)

1. Treatment is for chronic idiopathic constipation (CIC) or irritable bowel syndrome with constipation (IBS-C).
2. Failure of or intolerance to adequate trials of fiber supplement AND osmotic laxative (e.g. polyethylene glycol, lactulose).
3. If appropriate, will be approved for most cost-effective agent between lubiprostone, linaclotide, and plecanatide.
4. Approval for lubiprostone in IBS-C will be limited to female patients.

Linagliptin (Tradjenta®) – See Dipeptidyl peptidase-4 (DPP-4) inhibitors

Linezolid (Zyvox®)

1. IV vancomycin should be utilized when possible.
2. Case by case basis for transition of stable patients receiving IV vancomycin in hospital setting to institution which is unable to provide IV vancomycin.
3. Documentation of culture and sensitivity data must be submitted with non- formulary request.

Liraglutide (Victoza®, Saxenda®)

1. Not approved for DM1
2. WEIGHT LOSS: INITIAL REQUEST:
    a. Body Mass Index (BMI) ≥ 30 kg/m2 or BMI ≥ 27 kg/m2 with at least 1 weight-related comorbidity (e.g., hypertension, type 2 diabetes, dyslipidemia, metabolic syndrome, obstructive sleep apnea, osteoarthritis, non-alcoholic fatty liver disease) AND
    b. Verified lifestyle interventions (diet, physical activity, and counseling) for 6 months. Food and exercise logs, weight checks, commissary purchase records, and counseling with appropriate staff are verified in EHR. Inmate should be enrolled in at-risk program if available AND
    c. Completion of medication review to identify medications that can cause weight gain and change to alternatives when clinically appropriate AND
    d. Initial trial will be issued for 180 days for the most cost effective GLP1-agonist.
3. WEIGHT LOSS: POST TRIAL REQUEST:
    a. Has the patient been compliant with lifestyle interventions (i.e. participation in at-risk programs if available, commissary purchase review)? If not, requests for renewal will not be approved.
    b. Has patient lost = or > than 5% body weight from baseline? If not, requests for renewal will not be approved.

Lisdexamfetamine (Vyvanse®)

1. Patient has documented diagnosis of ADHD.
2. Psychotherapy, with psychology referral to include individual therapy to learn coping, organizational, prioritization, and anger management skills for a minimum of 6 months. Psychotherapy should continue if medication is initiated. (Concurrent treatment recommended rather than sequential treatment.)
3. Failure of ALL non-stimulant agents after ADEQUATE trials for each step for a minimum of 6 weeks. Patient self-reported trials of medication regimens and doses will not be accepted. All medications trials must have occurred and been documented within the BOP.
    a. Atomoxetine
    b. Atomoxetine plus guanfacine
    c. Atomoxetine plus clonidine
    d. Desipramine +/- atomoxetine
    e. Clonidine
    f. Bupropion
4. Submitted documentation must include/show the following:
    a. Copy of full psychiatric and psychological behavioral function evaluations
    b. Evidence (with specific examples) of inability to function in the correctional environment (e.g., incident reports)
    c. Doses of formulary medications have been maximized
    d. Six-week minimum trial of medication occurred at maximized dose
    e. Assessment for history of drug misuse including type of drug (e.g., stimulant, opiate, benzodiazepine)
5. If stimulant use approved, recommend utilizing methylphenidate immediate-release formulation as opposed to mixed amphetamine salts immediate-release formulation due to methylphenidate's shorter half-life. Requests for long-acting stimulants will not be approved.

6. The use of stimulants in persons with a history of stimulant drug misuse will not be approved.
7. For narcolepsy: Documented verification of the patient's report, to include polysomnography obtained and provided.
8. For narcolepsy: Patient has failed non-pharmacologic management strategies.
9. For narcolepsy: Functional impairment with work assignment, institution security, academic needs.
10. For narcolepsy: Failed treatment with modafinil and fluoxetine (for cataplexy).

Long-acting beta agonists (LABAs): arformoterol (Brovana®), formoterol (Perforomist®), olodaterol (Striverdi®), salmeterol (Serevent®)

1. Use of LABA in asthma is contraindicated when not used in combination with an ICS. Must provide clinical justification for why formulary combination LABA/ICS cannot be used.
2. When treatment with a LABA is initiated in COPD, the preferred choice is a combination LAMA/LABA product. Must provide clinical justification for why formulary LAMA monotherapy cannot be used.

Long-acting beta agonists (LABAs) / inhaled corticosteroids (ICS): budesonide/formoterol (Symbicort®), fluticasone/salmeterol (Advair® AirDuo®), mometasone/formoterol (Dulera®), fluticasone/vilanterol (Breo®)

1. COPD patients must have failed anticholinergic agent tiotropium (Spiriva®).
2. All inhaled corticosteroid/ long-acting beta-agonist (ICS/LABA) requests must be for fluticasone/salmeterol (Wixela Inhub®) per mandatory contract, unless clinically justified otherwise.

Long-acting beta agonists (LABAs) / inhaled long-acting muscarinic antagonists (LAMAs): glycopyrrolate/formoterol (Bevespi®), tiotropium/olodaterol (Stiolto®), umeclidinium/vilanterol (Anoro®)

1. COPD: Patients must have failed monotherapy with anticholinergic agent tiotropium (Spiriva®) or meet criteria defined by GOLD guidelines: "Group B": 0-1 moderate exacerbations not leading to hospital admission/year, modified Medical Research Council dyspnea questionnaire (mMRC) >/=2, and COPD Assessment Test (CAT) >/=10), or "Group E": >/=2 moderate exacerbations not leading to hospital admission/year, or at least 1 exacerbation leading to hospitalization/year
2. ASTHMA: Only to be used as part of a combination product with inhaled corticosteroid. Long-acting beta-agonist (LABA) not to be used as single-agent product or as combination product with long-acting muscarinic-antagonist (LAMA) in asthma.
3. Non-formulary requests for LABA/LAMA that meet criteria will be approved for most cost-effective agent.

Long-acting beta agonists (LABAs) / long-acting muscarinic antagonists (LAMAs) / inhaled corticosteroid (ICS): budesonide/glycopyrrolate/formoterol (Breztri®), fluticasone furoate/umeclidinium/vilanterol (Trelegy®)

1. New requests and renewals must contain documentation of counseling on inhaler technique and inhaler adherence.
2. COPD patient with a history of exacerbations requiring hospitalization or ≥ 2 moderate exacerbations/year and a blood eosinophil count of > 300 cells/µL. (Attach labs)
3. COPD: Patient with a history of 0-1 exacerbations and blood eosinophil < 300 cells/µL, should have history of trial of LABA+LAMA used concomitantly.

4. Asthma: patient failed high dose ICS/LABA combination. *Evidence to the benefits of triple therapy is limited in asthma – if asthma control not improved in 90-day trial, add-on should be discontinued
5. Triple agent is more cost-effective then formulary alternatives used in combination.

Loperamide (Immodium®)

1. Patient is indigent, treatment is medically necessary, AND has failed OTC Indigent program alternatives. Orders are limited to 30 days in duration.

Loratadine (Claritin®) – See Antihistamines (oral, non-sedating)

Lorazepam, long-term use – See Benzodiazepines

Loteprednol etabonate (Lotemax® Alrex®)

1. After use of formulary ophthalmic steroid for greater than 28 days.

Lubiprostone (Amitiza®)

1. Treatment is for chronic idiopathic constipation (CIC) or irritable bowel syndrome with constipation (IBS-C).
2. Failure of or intolerance to adequate trials of fiber supplement AND osmotic laxative (e.g. polyethylene glycol, lactulose).
3. If appropriate, will be approved for most cost-effective agent between lubiprostone, linaclotide, and plecanatide.
4. Approval for lubiprostone in IBS-C will be limited to female patients.

Lumateperone (Caplyta®)

1. Medication is being utilized to treat patients who carry diagnosis in BEMR for a schizophrenia spectrum disorder
2. Failure of three or more formulary oral antipsychotic treatment trials due to significant adverse reactions that are unable to be managed by dose reductions of the causative agent
3. Details related to prior antipsychotic treatment failures are documented in the above comments to include medications, doses, durations, compliance, and (as applicable) adverse drug reactions (ADRs).

Lurasidone (Latuda®)

1. Request is in accordance with the Schizophrenia and/or Bipolar Clinical Guidance documents or has justification as to why prescribing is different from recommendations in clinical guidance.
2. If weight gain is a concern, patient must have documented failure with or contraindications to formulary weight neutral options (aripiprazole and ziprasidone). Dose and duration of failed treatments as validated via eMAR. Must specify why weight gain is concerning in this patient (e.g., comorbid medical conditions, notably elevated BMI, etc.)

Macitentan (Opsumit®)

1. Patient is under the care of a specialist for the treatment of pulmonary hypertension AND
2. Patient is prescribed a phosphodiesterase-5 inhibitor, unless contraindicated or not tolerated.
3. Requests for endothelin receptor antagonists will be approved for ambrisentan, unless justification is provided for why this agent cannot be used.

Magnesium/aluminum/simethicone-containing products (Maalox®, Mylanta®, Gaviscon®, Milk of Magnesia®, etc.)

1. Patient is indigent, treatment is medically necessary, AND has failed OTC Indigent program alternatives . Orders are limited to 30 days in duration.

Maraviroc (Selzentry®) – See HIV medications

Memantine XR (Namenda®XR)

1. Failure of, or contraindication to, immediate release memantine.

Metaxalone (Skelaxin®) – See Muscle relaxants

Methotrexate auto-injector (Rasuvo ®, Otrexup®)

1. Oral methotrexate dose is at least 15 mg/week and is not effective OR not tolerated
2. Recommended by a rheumatologist
3. Institution does not have access to proper controls to prepare and administer more cost-effective methotrexate injection from a vial.
4. Requests shall be approved for the least expensive autoinjector product (ex. Rasuvo, Otrexup).

Methotrexate sodium injection

1. Hazardous antineoplastic drug. Does your institution have appropriate ventilated controls for preparation? If no, recommend using prefilled-autoinjector product instead for non-oncology uses.

Methylpenidate (Ritalin®)

1. Patient has documented diagnosis of ADHD.
2. Psychotherapy, with psychology referral to include individual therapy to learn coping, organizational, prioritization, and anger management skills for a minimum of 6 months. Psychotherapy should continue if medication is initiated. (Concurrent treatment recommended rather than sequential treatment.)
3. Failure of ALL non-stimulant agents after ADEQUATE trials for each step for a minimum of 6 weeks. Patient self-reported trials of medication regimens and doses will not be accepted. All medications trials must have occurred and been documented within the BOP.
    a. Atomoxetine
    b. Atomoxetine plus guanfacine
    c. Atomoxetine plus clonidine
    d. Desipramine +/- atomoxetine
    e. Clonidine
    f. Bupropion
4. Submitted documentation must include/show the following:
    a. Copy of full psychiatric and psychological behavioral function evaluations
    b. Evidence (with specific examples) of inability to function in the correctional environment (e.g., incident reports)
    c. Doses of formulary medications have been maximized
    d. Six-week minimum trial of medication occurred at maximized dose
    e. Assessment for history of drug misuse including type of drug (e.g., stimulant, opiate, benzodiazepine)

5. If stimulant use approved, recommend utilizing methylphenidate immediate-release formulation as opposed to mixed amphetamine salts immediate-release formulation due to methylphenidate's shorter half-life. Requests for long-acting stimulants will not be approved.
6. The use of stimulants in persons with a history of stimulant drug misuse will not be approved.
7. For narcolepsy: Documented verification of the patient's report, to include polysomnography obtained and provided.
8. For narcolepsy: Patient has failed non-pharmacologic management strategies.
9. For narcolepsy: Functional impairment with work assignment, institution security, academic needs.
10. For narcolepsy: Failed treatment with modafinil and fluoxetine (for cataplexy).

Metoclopramide (Reglan®)

1. Restricted to 12 weeks of therapy for all formulations
2. If NFR approved, after 12 weeks, get periodic AIMS testing

Minocycline, oral

1. Acne: Treatment of moderate or severe acne.
2. Acne: Failure of at least 2 topical agents.

Mirabegron (Myrbetriq®) – See Beta-3 adrenergic agonists

Mitoxantrone (Novantrone®)

1. Prescribed by, or in consultation with, a neurologist or other appropriate specialist for the treated disease state.
2. Confirmed diagnosis of relapsing forms of multiple sclerosis – including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
3. Failure (or use contraindicated) of formulary options or justification why formulary options cannot be used.

Modafinil (Provigil®)

1. For narcolepsy: Documented verification of the patient's report, to include polysomnography obtained and provided.
2. For narcolepsy: Patient has failed non-pharmacologic management strategies.
3. For narcolepsy: Functional impairment with work assignment, institution security, academic needs.
4. For narcolepsy: Failed treatment with modafinil and fluoxetine (for cataplexy).

Moisturizers (topical): all formulations except Vitamins A and D

1. Failed a 30-day trial of two commissary moisturizers OR
2. Patient is indigent AND treatment is medically necessary. Orders are limited to 30 days in duration when approved on the basis of indigent status alone. If renewed, indigent status will be reassessed.

Mometasone nasal spray (Nasonex®) – See Steroid nasal sprays

Monomethyl fumarate (Bafiertam®)

1. Prescribed by, or in consultation with, a neurologist or other appropriate specialist for the treated disease state.

2. Confirmed diagnosis of relapsing forms of multiple sclerosis – including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
3. Failure (or use contraindicated) of formulary options or justification why formulary options cannot be used.

Montelukast (Singulair®)

1. Asthma: Third line agent in the treatment of asthma. Compliance with other medications must be shown (e.g. oral steroid inhalers).
2. Allergic Rhinitis: Third line agent after documented compliance with OTC antihistamine and nasal steroid. Copies of progress notes detailing symptoms and exam findings will be required.
3. Urticaria: Montelukast will not be approved for this indication.

Muscle relaxants: dantrolene (Dantrium®), baclofen (Lioresal®), cyclobenzaprine (Flexeril®), tizanidine (Zanaflex®), metaxalone (Skelaxin®), methocarbamol (Robaxin®), carisprodal (Soma®), chlorzoxazone (Parafon Forte DSC®), orphenadrine (Norflex®)

Approval for muscle relaxants will be considered for the following cases and all must be administered via DIRECTLY OBSERVED THERAPY:

1. Observable, documented muscle spasm due to:
    a. Multiple sclerosis
    b. Spinal cord injury or intrinsic cord lesions (not herniated spinal discs, not low back pain due to muscle spasm)
    c. Stroke
    d. Cerebral palsy
2. Approval for baclofen may be considered for intractable pain from neurological conditions, such as trigeminal neuralgia, that has been unresponsive to formulary agents.
3. Metaxalone is last resort skeletal muscle therapy after failure of all other muscle relaxants.

Naltrexone/bupropion (Contrave®)

1. Failure of all non-controlled substance alternatives for weight loss.

Naphazoline/pheniramine ophthalmic drops (Visine-A®, Opcon-A®)

1. Initiated by an optometrist or ophthalmologist, with ongoing evaluation AND
2. Failure of commissary alternatives OR patient is indigent AND treatment is medically necessary. Orders are limited to 3 days.

Natalizumab (Tysabri®)

1. Prescribed by, or in consultation with, a neurologist or other appropriate specialist for the treated disease state.
2. Confirmed diagnosis of relapsing forms of multiple sclerosis – including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
3. Failure (or use contraindicated) of formulary options or justification why formulary options cannot be used.

Nemoluzimab (Nucala®)

1. Patient has been diagnosed with moderate to severe atopic dermatitis by a dermatologist AND
2. Self-management with fragrance-free moisturizers has been tried for at least 6 continuous weeks without symptom improvement AND
3. Patient has a contraindication to, intolerability to, or have failed at least 12 weeks of treatment with at least ONE medication in EACH of the following categories: AND
    a. High potency/class 1 topical corticosteroids
    b. Topical calcineurin inhibitor
4. Patients has an allergy, documented intolerance, or failure with an adequate trial of dupilumab or tralokinumab.
5. If all other criteria are met, the least costly biologic for the requested indication at the time of request will be approved.

Netarsudil (Rhopressa®) ophthalmic solution

1. Diagnosis of open-angle glaucoma or ocular hypertension AND
2. Initiated by optometrist or ophthalmologist with ongoing evaluation AND
3. Inadequate response/failure of three formulary agents (e.g., Latanaprost, dorzolamide/timolol (or individual agents), brimonidine).

Nutritional supplements for oral consumption

1. Request for its non-formulary use requires clinical justification from a BOP registered dietitian or completion of the Nutritional Supplements Worksheet.
2. Failure of medical diets, special diets, and supplemental feeding options available through Food Service, AND
3. A documented medical diagnosis affecting nutritional status, AND
4. Nutritional Assessment Consult by BOP registered dietitian for therapy > 30 days.

Ocrelizumab (Ocrevus®)

1. Prescribed by, or in consultation with, a neurologist or other appropriate specialist for the treated disease state.
2. Confirmed diagnosis of relapsing forms of multiple sclerosis – including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
3. Failure (or use contraindicated) of formulary options or justification why formulary options cannot be used.

Ofatumumab (Kesimpta®)

1. Prescribed by, or in consultation with, a neurologist or other appropriate specialist for the treated disease state.
2. Confirmed diagnosis of relapsing forms of multiple sclerosis – including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
3. Failure (or use contraindicated) of formulary options or justification why formulary options cannot be used.

Olanzapine pamoate intramuscular injection (Zyprexa® Relprevv□)

1. Non-compliance to oral antipsychotic therapy documented on eMAR.
2. Provider, pharmacy, and patient are enrolled in Relprevv® risk evaluation mitigation (REMS) program.
3. Institution has proper staffing to monitor for post-injection delirium/sedation syndrome (PDSS) for 3 hours after each injection.
4. Patients with a history of cardiovascular disease have been educated on signs and symptoms of postural hypotension and bradycardia.
5. Patient has documented failure to alternative long acting injectable (LAI) second generation antipsychotics or justification as to why alternatives cannot be utilized is explained in the comments above.
6. If patient currently stable on oral olanzapine and compliance concerns are the basis for this non-formulary submission, utilization of olanzapine orally disintegrating tablets (ODT) has been considered and justification for why they cannot be utilized is given in the comments section.
7. Appropriate monitoring related to diabetes, dyslipidemia, and weight gain has been ordered and patient will be educated on ways to mitigate these associated adverse reactions to the medication.

Omalizumab (Xolair®)

1. ASTHMA
    a. The patient has persistently uncontrolled asthma after a reasonable trial of high-dose ICS/LABA and antileukotriene (e.g., montelukast).
    b. The patient completed observed inhaler technique with correction as needed.
    c. The patient has severe uncontrolled asthma with an allergic component confirmed via positive skin tests or in vitro reactivity to a perennial allergen.
    d. Pre-treatment serum IgE is 30 to 700 IU/mL
2. ATOPIC DERMATITIS
    a. Patient has been diagnosed with moderate to severe atopic dermatitis by a dermatologist AND
    b. Self-management with fragrance-free moisturizers has been tried for at least 6 continuous weeks without symptom improvement AND
    c. Patient has a contraindication to, intolerability to, or have failed at least 12 weeks of treatment with at least ONE medication in EACH of the following categories: AND
        i. High potency/class 1 topical corticosteroids
        ii. Topical calcineurin inhibitor
    d. Patients has an allergy, documented intolerance, or failure with an adequate trial of dupilumab or tralokinumab.
    e. If all other criteria are met, the least costly biologic for the requested indication at the time of request will be approved.
3. URTICARIA
    a. Documented chronic or spontaneous idiopathic urticaria for 6 weeks or longer.
    b. Insufficient symptom relief after adequate trials of each of the below agents, documented in BEMR or via commissary sales within the last 90 days.
        i. TWO second generation antihistamines titrated up to the maximum daily dose as tolerated,
        ii. AND an H_2 antagonist,
        iii. AND a first-generation antihistamine or doxepin at bedtime.

4. SINUSITIS:
    a. Documented chronic rhinosinusitis with nasal polyps and failure of adequate trial of intranasal corticosteroids.
    b. Pre-treatment serum IgE level 30 to 1,500 IU/mL.
5. FOOD ALLERGIES:
    a. Documentation of IgE mediated severe food allergies that cannot be mitigated through avoidance.
    b. Pre-treatment serum IgE level 30 to 1,850 IU/mL
    c. Omalizumab is NOT indicated for emergency treatment of allergic reactions, including anaphylaxis. Patient must have a concomitant order for an epinephrine auto-injector.
6. ALL indications: Omalizumab recommended by a specialist. (Please upload in Document Manager.)

Omega-3 fatty acid ethyl esters (Lovaza®)

1. Icosapent ethyl (Vascepa®) is the preferred omega 3 fatty acid agent.
2. Prior failure of or contraindication to icosapent omega-3 fatty acid (Vascepa®) AND
3. Failure to achieve therapeutic triglyceride level (<150 mg/dL) with maximally tolerated statin AND established cardiovascular disease (ASCVD) or diagnosis of diabetes, or high risk for CV events (ASCVD risk >7.5%) OR
4. Severe hypertriglyceridemia (≥ 500 mg/dL) or unable to take fenofibrate.

Orlistat (Xenical®, Alli®OTC)

1. INITIAL REQUEST:
    a. Body Mass Index (BMI) ≥ 30 kg/m2 or BMI ≥ 27 kg/m2 with at least 1 weight-related comorbidity (e.g., hypertension, type 2 diabetes, dyslipidemia, metabolic syndrome, obstructive sleep apnea, osteoarthritis, non-alcoholic fatty liver disease) AND
    b. Verified lifestyle interventions (diet, physical activity, and counseling) for 6 months. Food and exercise logs, weight checks, commissary purchase records, and counseling with appropriate staff are verified in EHR. Inmate should be enrolled in at-risk program if available AND
    c. Completion of medication review to identify medications that can cause weight gain and change to alternatives when clinically appropriate
2. POST TRIAL REQUEST:
    a. Has the patient been compliant with lifestyle interventions (i.e. participation in at-risk programs if available, commissary purchase review)? If not, requests for renewal will not be approved.
    b. Has patient lost = or > than 5% body weight from baseline? If not, requests for renewal will not be approved.

Oseltamivir (Tamiflu®)

1. Use within 48 hours of symptom onset.
2. May be initiated more than 48 hours after symptom onset but no more than five days after symptom onset for patients that may progress to requiring hospitalization and for pregnant patients (of any trimester).
3. Non-Formulary Drug requests for TamiFlu® will be processed and expedited through Central Office.
4. Treatment requests for outbreaks, prophylaxis, and exposures will be conducted through the Infectious Disease Coordinator. Region, Central Office and approved by the BOP Medical Director for treatment.

5. **NOTE:** Stockpile antivirals may only be approved for use by the BOP Medical Director under certain conditions as proclaimed by the World Health Organizations.

Oxcarbamazepine oral (Trileptal®)

1. Bipolar disorder: Patient failed therapy (or use contraindicated) with lithium, lamotrigine, valproate, and/or second-generation antipsychotics
2. Pain management: Patient failed therapy (or use contraindicated) with SNRIs, TCAs and gabapentin.
3. Consider a directly-observed therapy restriction (pill-line only) for patients with a history of medication misuse.

Oxycodone controlled release (CR) (OxyContin®)

1. Must have failed extended-release morphine. Failure is defined as unable to titrate dose due to adverse effects unable to be resolved despite aggressive treatment.

Ozanimod (Zeposia®)

1. Prescribed by, or in consultation with, a neurologist or other appropriate specialist for the treated disease state.
2. Confirmed diagnosis of relapsing forms of multiple sclerosis – including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
3. Failure (or use contraindicated) of formulary options or justification why formulary options cannot be used.

Paliperidone palmitate ER (Invega Sustenna®, Erzofri®)

1. Patient is stable on oral paliperidone, oral risperidone, or long-acting risperidone AND
2. Inadequate response to risperidone long-acting injection (Risperdal Consta®)
3. Requests for patients stabilized on paliperidone palmitate ER will be approved for continuity of care

Paliperidone palmitate ER (Invega Trinza®)

1. Patient has been stable for at least 4 months on paliperidone palmitate (Invega Sustenna®) AND
2. Inadequate response to risperidone long-acting injection (Risperdal Consta®)
3. Requests for patients stabilized on paliperidone palmitate ER will be approved for continuity of care

Paliperidone palmitate ER (Invega Halfyera®)

1. Patient has been stable for at least 4 months on paliperidone palmitate (Invega Sustenna®) OR at least 1 month on paliperidone palmitate ER (Invega Trinza®) AND
2. Inadequate response to risperidone long-acting injection (Risperdal Consta®)
3. Requests for patients stabilized on paliperidone palmitate ER will be approved for continuity of care

PCSK9 inhibitors: evolocumab (Repatha®), alirocumab (Praluent®)

1. Prescribed for an FDA approved indication only.
2. Failure to achieve cholesterol goals with maximum doses of at least two different HmgCoA reductase inhibitors, OR
3. Unable to tolerate HmgCoA reductase inhibitors.

Pegylated interferon beta-1a (Plegridy®)

1. Prescribed by, or in consultation with, a neurologist or other appropriate specialist for the treated disease state.
2. Confirmed diagnosis of relapsing forms of multiple sclerosis – including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
3. Failure (or use contraindicated) of formulary options or justification why formulary options cannot be used.

Phenobarbital (Luminal®)

1. Diagnosis of seizure **AND**
2. Used in combination with other anticonvulsant medications **AND**
3. Used as third-line agent **AND**
4. Compliance > 90% maintained.

Phentermine/topiramate (Qsymia®)

1. Failure of all non-controlled substance alternatives for weight loss.
2. Request must include confirmation of REMS enrollment.

Plecanatide (Trulance®)

1. Treatment is for chronic idiopathic constipation (CIC) or irritable bowel syndrome with constipation (IBS-C).
2. Failure of or intolerance to adequate trials of fiber supplement AND osmotic laxative (e.g. polyethylene glycol, lactulose).
3. If appropriate, will be approved for most cost-effective agent between lubiprostone, linaclotide, and plecanatide.
4. Approval for lubiprostone in IBS-C will be limited to female patients.

Ponesimod (Ponvory®)

1. Prescribed by, or in consultation with, a neurologist or other appropriate specialist for the treated disease state.
2. Confirmed diagnosis of relapsing forms of multiple sclerosis – including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
3. Failure (or use contraindicated) of formulary options or justification why formulary options cannot be used.

Potassium-lowering agents: sodium zirconium cyclosilicate (Lokelma®), patiromer (Veltassa®)

1. Persistent or recurrent serum potassium ≥ 5.5 mEq/L despite the following measures to manage hyperkalemia:
    a. Adjustment or discontinuation of medications that may contribute to hyperkalemia (i.e. potassium supplements, ACE inhibitors, ARBs, ARN inhibitors, MRAs, NSAIDs), if appropriate. Consider clinical practice guidelines and risk vs. benefit of continued use.
    b. Initiation or adjustment of diuretic therapy (loop or thiazide), if appropriate
    c. Patient education regarding a low potassium diet and avoidance of potassium salt substitutes
2. If patient has Chronic Kidney Disease (CKD), consultation with nephrology

Prasugrel (Effient®)

1. Patient has clopidogrel allergy**.**
2. Patient failed clopidogrel therapy.
3. Is patient on pharmacotherapy that has major interaction with clopidogrel but does not interact with prasugrel?
4. Patient has an active pathologic bleed or has a history of transient ischemic attack (TIA) or stroke? (Contraindicated**)**
5. Patient over the age of 74? (Not recommended, increases bleeding risk)
6. Patient weighs less than 60kg, is prone to bleeding and/or concomitant use of medications that increase the risk of bleeding (eg, warfarin, heparin, fibrinolytic therapy, long-term use of NSAIDs? (Risk factors for bleeding)

Pregabalin (Lyrica®)

1. Approved for neuropathic pain after failure of duloxetine, plus at least one other medication from the tricyclic antidepressant category.
2. Postherpetic Neuralgia - well documented intolerance or insufficient functional response at maximally tolerated doses of tricyclic antidepressants and topical analgesics such as capsaicin cream
3. Fibromyalgia - documented diagnosis of fibromyalgia by rheumatologist. Documented insufficient functional response to duloxetine, plus at least one other medication from the tricyclic antidepressant or antiepileptic categories.
4. Partial onset seizures - well documented intolerance or insufficient response to at least two other agents (i.e. Carbamazepine, lamotrigine, levetiracetam, phenytoin, topiramate).

Protein powder/liquid

1. Request for its non-formulary use requires completion of the Nutritional Supplements Worksheet.
2. Failure of medical diets, special diets, and supplemental feeding options available through Food Service, **AND**
3. A documented medical diagnosis affecting nutritional status, **AND**
4. Nutritional Assessment Consult by BOP registered dietician required for every request.

Prucalopride (Motegrity®)

1. Treatment is for chronic idiopathic constipation (CIC).
2. Failure of or intolerance to adequate trials of fiber supplement AND osmotic laxative (i.e., polyethylene glycol, lactulose).
3. Failure of or intolerance to adequate trials of lubiprostone, linaclotide, AND plecanatide.

Quetiapine (Seroquel®)

1. Use in psychotic disorder, bipolar disorder, or borderline personality disorders only.
2. Requests must include justification and treatment history in accordance with the Antipsychotic Treatment Algorithm, BOP Clinical Practice Guidelines, Pharmacological Management of Schizophrenia.
3. Non-formulary approvals for oral formulation will be restricted to the IR formulation only. Quetiapine IR must be administered via directly observed therapy and crushed prior to administration unless otherwise restricted by package insert.

Quinine

Non-formulary requests will not be approved for leg cramps.

Ramelteon (Rozerem®)

1. Patient has documented diagnosis of insomnia
2. Insomnia relates specifically to time to sleep onset and NOT sleep maintenance
3. Clear documentation of how insomnia is negatively affecting a secondary diagnosis or functional status is explained above in the comments AND in a BEMR encounter
4. Medication is recommended by a sleep specialist or a psychiatrist
5. Patient has received sleep hygiene counseling, it is documented in Patent Education, AND the date(s) it was provided is listed above.
6. Patient has documented failure to a adequate trials of at least three (3) formulary agents to include a TCA (e.g., amitriptyline, doxepin, etc.), mirtazapine, and trazodone or justification as to why these medications cannot be utilized is explained in the comments above.
7. Patient does NOT have a history of severe sleep apnea or severe hepatic impairment.
8. Patient is NOT currently prescribed any strong CYP1A2 inhibitors (e.g., fluvoxamine).

Rifaximin (Xifaxan®)

1. Treatment of hepatic encephalopathy
2. Patient refractory to lactulose (patient obtained 3 loose stool per day)
3. Patient intolerant to lactulose

Rimegepant (Nurtec®ODT) – See Calcitonin gene-related peptide (CGRP) antagonists (small-molecule)

Riociguat (Adempas®)

1. Patient is under the care of a specialist for the treatment of pulmonary hypertension AND
2. May be considered as an alternative to PDE-5 inhibitor in intermediate-low risk patients not reaching goal on endothelin receptor antagonist plus phosphodiesterase-5 inhibitor.

Salicylic acid: external patch 40%, solution/gel 17%

1. Patient is indigent AND treatment medically necessary. Orders are limited to 60 days in duration when approved on the basis of indigent status alone. If renewed, indigent status will be reassessed.

Salmeterol (Serevent®) – See Long-acting beta agonists (LABAs)

Sarecycline (Seysara®)

1. Acne: Treatment of moderate or severe acne.
2. Acne: Failure of at least 2 topical agents.

Saxagliptin (Onglyza®) – See Dipeptidyl peptidase-4 (DPP-4) inhibitors

Scopolamine patch (Transderm Scop®)

1. Motion sickness refractory to oral formulation meclizine or dimenhydrinate OR
2. Surgery with anesthesia within 24 hours of first dose, approved up to 24 hours after surgery OR
3. Terminal secretions not otherwise managed with sublingual atropine

Selenium shampoo/lotion

1. Documented failure of OTC commissary selenium or coal tar shampoo OR
2. Patient is indigent, treatment medically necessary AND has failed OTC Indigent Program alternatives (ex: Selenium Shampoo 1%Shampoo). Orders are limited to 30 days in duration when approved on the basis of indigent status alone. If renewed, indigent status will be reassessed.

Selexipag (Uptravi®)

1. Patient is under the care of a specialist for the treatment of pulmonary hypertension.

Semaglutide (Rybelsus®, Wegovy®, Ozempic)

1. Not approved for DM1
2. WEIGHT LOSS: INITIAL REQUEST:
    a. Body Mass Index (BMI) ≥ 30 kg/m2 or BMI ≥ 27 kg/m2 with at least 1 weight-related comorbidity (e.g., hypertension, type 2 diabetes, dyslipidemia, metabolic syndrome, obstructive sleep apnea, osteoarthritis, non-alcoholic fatty liver disease) AND
    b. Verified lifestyle interventions (diet, physical activity, and counseling) for 6 months. Food and exercise logs, weight checks, commissary purchase records, and counseling with appropriate staff are verified in EHR. Inmate should be enrolled in at-risk program if available AND
    c. Completion of medication review to identify medications that can cause weight gain and change to alternatives when clinically appropriate AND
    d. Initial trial will be issued for 180 days for the most cost effective GLP1-agonist.
3. WEIGHT LOSS: POST TRIAL REQUEST:
    a. Has the patient been compliant with lifestyle interventions (i.e. participation in at-risk programs if available, commissary purchase review)? If not, requests for renewal will not be approved.
    b. Has patient lost = or > than 5% body weight from baseline? If not, requests for renewal will not be approved.

Sildenafil (Revatio®)

1. Patient is under the care of a specialist for the treatment of pulmonary hypertension.

Simethicone tablets/capsules (Gas-X®)

1. Patient is indigent AND treatment is medically necessary. Orders are limited to 30 days in duration when approved on the basis of indigent status alone. If renewed, indigent status will be reassessed.

Siponimod (Mayzent®)

1. Prescribed by, or in consultation with, a neurologist or other appropriate specialist for the treated disease state.
2. Confirmed diagnosis of relapsing forms of multiple sclerosis – including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
3. Failure (or use contraindicated) of formulary options or justification why formulary options cannot be used.

Sitagliptin (Januvia®) – See Dipeptidyl peptidase-4 (DPP-4) inhibitors

Sotatercept (Winrevair®)

1. Patient under the care of a specialist for the treatment of pulmonary hypertension AND
2. Patient is stabilized on dual or triple therapy for pulmonary arterial hypertension for at least 30 days AND
3. Risk factors for bleeding have been considered and addressed, including evaluating the continued need for drugs that increase bleeding risk.

Steroid nasal sprays: beclomethasone AQ (Beconase®), fluticasone (Flonase®), mometasone (Nasonex®), triamcinolone (Nasacort®)

1. Failure of commissary steroid nasal spray and saline nasal spray (or cromolyn nasal spray) within the last 90 days.
2. Patient is indigent AND treatment is medically necessary. Orders are limited to 30 days in duration when approved based on indigent status alone. If renewed, indigent status will be reassessed.

Sulfamethoxazole/trimethoprim, oral

1. Acne: Treatment of moderate or severe acne.
2. Acne: Failure of at least 2 topical agents.

Sunscreen (various formulations)

1. Prescribed an essential medication causing documented photosensitivity *OR*
2. Patient is indigent AND treatment is medically necessary. Orders are limited to 30 days in duration when approved on the basis of indigent status alone. If renewed, indigent status will be reassessed.
3. Requests due to unavailability of protective clothing will be disapproved.
4. Approvals will be for SPF 30 products only.

Tacrolimus topical (Protopic®)

1. Patient has failed topical emollients/moisturizers.
2. Patient has failed topical corticosteroids.
3. Patient requires application to sensitive areas such as face or skin folds.

Tadalafil (Adcirca®)

1. Patient is under the care of a specialist for the treatment of pulmonary hypertension.

Tbo-filgrastim (Granix®) – See Granulocyte colony-stimulating factors (G-CSFs)

Terbinafine oral

1. Diabetic or circulatory disorders evidenced by absence of pedal pulses and/or extremity hair loss due to poor circulation, or abnormal monofilament exam demonstrating loss of sensation, OR
2. Fungal nail infection (onychomycosis) with presence of secondary bacterial co-infection, OR
3. Patient is immunocompromised.
4. Onychomycosis requests meeting criteria will be approved for terbinafine (Lamisil®) 250 mg daily for 6 to 12 weeks for fingernails or toenails respectively.

Testosterone (Androgel®, Androderm®, Axiron®, Aveed®, Delatestryl®, Depo-Testosterone®, Fortesta®)

1. Evidence of pituitary adenoma, hypothalamic adenoma, or other confirmed disease of the testes, pituitary or hypothalamus.
2. Testosterone supplementation is not approved or continued for unlabeled uses, e.g., strength training, increased libido.
3. A six-month washout period is required for patients with no confirmed disease of the testes, pituitary or hypothalamus
4. Laboratory AND clinical evidence of testosterone deficiency (e.g., fatigue, depression, mood swings; decrease in pubic hair, hematocrit etc.) is confirmed after the 6-month washout period.
5. Two baseline serum total testosterone levels of < 300 ng/dL within the last 12 months, at least 1 week apart, drawn fasting, between 8:00 a.m. and 10:00 a.m.

Tetracycline, oral

1. Acne: Treatment of moderate or severe acne.
2. Acne: Failure of at least 2 topical agents.

Thickening Agents (Thick-It®etc.)

1. Requires swallow study for approval.

Tiagabine (Gabitril®)

1. Prescribed as adjunctive treatment for focal seizures AND
2. Recommended by a neurologist AND
3. Patient has failed adequate trial of two or more formulary antiepileptics AND
4. Patient is currently/will be maintained on one or more additional first-line antiepileptics.

Ticagrelor (Brilinta®)

1. Recommended by a cardiologist. (Please upload consult in Document Manager.)

Tipranavir (Aptivus®) – See HIV medications

Tirzepatide (Mounjaro®, Zepbound®)

1. Not approved for DM1
2. WEIGHT LOSS: INITIAL REQUEST:
    a. Body Mass Index (BMI) ≥ 30 kg/m2 or BMI ≥ 27 kg/m2 with at least 1 weight-related comorbidity (e.g., hypertension, type 2 diabetes, dyslipidemia, metabolic syndrome, obstructive sleep apnea, osteoarthritis, non-alcoholic fatty liver disease) AND
    b. Verified lifestyle interventions (diet, physical activity, and counseling) for 6 months. Food and exercise logs, weight checks, commissary purchase records, and counseling with appropriate staff are verified in EHR. Inmate should be enrolled in at-risk program if available AND
    c. Completion of medication review to identify medications that can cause weight gain and change to alternatives when clinically appropriate AND
    d. Initial trial will be issued for 180 days for the most cost effective GLP1-agonist.
3. WEIGHT LOSS: POST TRIAL REQUEST:

a. Has the patient been compliant with lifestyle interventions (i.e. participation in at-risk programs if available, commissary purchase review)? If not, requests for renewal will not be approved.
b. Has patient lost = or > than 5% body weight from baseline? If not, requests for renewal will not be approved.

Topiramate (Topamax®)

1. Medication is being used for the treatment of Refractory Bipolar Disorder or Refractory Borderline Personality Disorder.
2. Bipolar Disorder: Patient has failed treatment with or has contraindication to formulary options: valproic acid/divalproex, lithium, aripiprazole, olanzapine, risperidone, and carbamazepine.
3. Borderline Personality Disorder: Provider is targeting symptoms of affective dysregulation, impulsivity, and/or aggression.
4. Borderline Personality Disorder: Patient has failed treatment with or has contraindications to multiple formulary agents (E.G., valproic acid/divalproex, aripiprazole, ziprasidone, olanzapine, and haloperidol).
5. Seizures: Prescribed for the treatment of generalized focal seizures or tonic-clonic seizures.

Tralokinumab (Adbry®)

1. ATOPIC DERMATITIS
    a. Patient has been diagnosed with moderate to severe atopic dermatitis by a dermatologist AND
    b. Self-management with fragrance-free moisturizers has been tried for at least 6 continuous weeks without symptom improvement AND
    c. Patient has a contraindication to, intolerability to, or have failed at least 12 weeks of treatment with at least ONE medication in EACH of the following categories:
    d. High potency/class 1 topical corticosteroids
    e. Topical calcineurin inhibitor
    f. If all other criteria are met, the least costly biologic for the requested indication at the time of request will be approved.

Treprostinil (Remodulin®)

1. Patient is under the care of a specialist for the treatment of pulmonary hypertension.

Triamcinolone nasal spray (Nasacort®) – See Steroid nasal sprays

Trospium (Sanctura®, Sanctura XR®)

1. Failure of or intolerance to adequate trial of one formulary antimuscarinic agent (e.g., oxybutynin IR, oxybutynin ER, tolterodine ER, or solifenacin).

Ublituximab (Briumvi®)

1. Prescribed by, or in consultation with, a neurologist or other appropriate specialist for the treated disease state.
2. Confirmed diagnosis of relapsing forms of multiple sclerosis – including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
3. Failure (or use contraindicated) of formulary options or justification why formulary options cannot be used.

Ubrogepant (Ubrelvy®) – See Calcitonin gene-related peptide (CGRP) antagonists (small-molecule)

Upadacitinib (Rinvoq®)

1. Patient has been diagnosed with moderate to severe atopic dermatitis by a dermatologist AND
2. Self-management with fragrance-free moisturizers has been tried for at least 6 continuous weeks without symptom improvement AND
3. Patient has a contraindication to, intolerability to, or have failed at least 12 weeks of treatment with at least ONE medication in EACH of the following categories: AND
    a. High potency/class 1 topical corticosteroids
    b. Topical calcineurin inhibitor
4. Patients has an allergy, documented intolerance, or failure with an adequate trial of dupilumab or tralokinumab.
5. If all other criteria are met, the least costly biologic for the requested indication at the time of request will be approved.

Vigabatrin (Sabril®)

1. Prescribed for the treatment of refractory complex partial seizures AND
2. Prescribed/recommended by a neurologist AND
3. Patient has failed adequate trial of three or more antiepileptics AND
4. Patient is properly enrolled in required REMS program AND
5. Initial request will be approved for 60 days pending initial evaluation.

Vibegron (Gemtesa®) – See Beta-3 adrenergic agonists

Viloxazine ER (Qelbree®)

1. Preferred formulary agents for ADHD are atomoxetine, guanfacine, and desipramine.
2. Preferred non-formulary agents for ADHD are clonidine and bupropion.
3. Reserved for failure of adequate trials (confirmed compliance > 6 weeks) of ALL of the following medications: atomoxetine, atomoxetine plus guanfacine, atomoxetine plus clonidine, desipramine, and bupropion.

Vitamin A and D ointment

1. Diabetes with Neuropathy OR
2. Circulatory disorder evidenced by absence of pedal pulses and/or extremity hair loss due to poor circulation, or abnormal monofilament exam demonstrating loss of sensation OR
3. Patient is indigent AND treatment medically necessary. Orders are limited to 30 days in duration when approved on the basis of indigent status alone. If renewed, indigent status will be reassessed.

Voxelotor (Oxbryta®)

1. Diagnosis of sickle cell disease and prescribed by or in consultation with a hematologist.
2. Trial (at least 3 months) or current treatment with hydroxyurea.
3. At least 1 vaso-occlusive crisis in the last 12 months, and hemoglobin between 5.5 g/dL and 10.5 g/dL. Initial requests will be approved for 6 months.
4. Renewal requests: Documented improvement in hemoglobin of ≥ 1 g/dL from baseline AND
5. Decrease in number of vaso-occlusive crises by ≥ 1 crisis per year from previous year baseline.

Witch hazel and glycerin pads topical (Tucks®Pads)

1. Pending hemorrhoid surgery or 30 days (or less) post-hemorrhoid surgery OR
2. Patient is indigent AND treatment is medically necessary. Orders are limited to 30 days in duration when approved on the basis of indigent status alone. If renewed, indigent status will be reassessed.

Zanamivir (Relenza®)

1. Therapy is only to be offered to patients within 48 hours of exposure. Antiviral therapy is not effective or recommended 48 hours post exposure.
2. Non-Formulary Drug requests for TamiFlu® will be processed and expedited through Central Office.
3. Treatment requests for outbreaks, prophylaxis, and exposures will be conducted through the Infectious Disease Coordinator. Region, Central Office and approved by the BOP Medical Director for treatment.
4. **NOTE:** Stockpile antivirals may only be approved for use by the BOP Medical Director under certain conditions as proclaimed by the World Health Organization.

Zonisamide (Zonegran®)

1. Previous medications, doses, and documented compliance; blood levels when appropriate.
2. EEG or clinical evidence of failure to achieve seizure-free state.
3. Documented adverse effects of formulary medications.
4. Results of any neurologic consultations.
5. Prescribed for the treatment of partial-onset seizures AND
6. Prescribed/recommended by a neurologist AND
7. Patient has failed an adequate trial of two or more other antiepileptics.

Federal Bureau of Prisons
National Formulary Part 1 Summer 2025

Worksheet for Use of Nutritional Supplements

Patient Name:	**Register Number:**	**Institution:**
Date of Birth:	**Usual Body Weight (lb):**	
Weight(lb):	**Height(in):**	**Gender: M / F**
BMI *(= 703 x [weight(lb) / height^2(in)])*:		
Ideal Weight Range (lb):__to _____ *Hamwi method: men = 106 lb + 6 lb for each inch >5 ft, women = 100 lb + 5 lb for each inch > 5 ft, then +/- 10% for range*		
Percent Weight Loss(%), unintentional: Over past month_, past 3 months__, past 6 months__ *Percent weight loss = (UBW – current weight / UBW) x 100*		

Medical Diagnoses – check all that apply (must have at least one):

- ☐ Dysphagia
- ☐ Crohn's Disease
- ☐ Alzheimer's Disease
- ☐ Swallowing Problems
- ☐ Mastication Problems
- ☐ Ulcerative Colitis
- ☐ Malabsorptive Disorder – Specify_____
- ☐ Failure to Thrive
- ☐ Burns - % Body Surface Area_____
- ☐ Hunger Strike
- ☐ Cancer
- ☐ End Stage Renal Disease on Dialysis
- ☐ Multiple Dental Extractions or Extensive Dental Surgery (short term use)
- ☐ Chronic Wounds (describe in notes below)
- ☐ Other(s): _____

BOP Food Service Diet(s)Tried – check all that apply:

- ☐ Regular
- ☐ Soft
- ☐ Mechanical Soft/Edentulous
- ☐ Low Residue / Low Fiber
- ☐ Clear Liquid
- ☐ Full Liquid
- ☐ Pureed
- ☐ Gluten Free
- ☐ Diabetic Snack
- ☐ Snack for Increased Calories

Reason(s) Nutritional Needs Could Not be Met Through Food Service Offerings:

Additional notes:

Name / Title / Signature of Requestor: **Date:**

Procedure for Submitting Nutritional Supplement Algorithm:

- Scan into BEMR Document Manager as .pdf file
- Attach to BEMR non-formulary request for selected nutritional supplement and/or protein powder/liquid when the patient has not been evaluated a BOP dietitian.
- For nutritional supplement use > 30 days and ALL protein-only supplement requests:
- a BOP registered dietitian nutritional assessment consult must be attached (completed locally at MRCs or via tele-nutrition at all others)

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Non-Sterile Compounding Worksheet

Attach this worksheet, along with any other required documentation with your NFR request.

Requesting Institution _____ Date_____

Who is making the compound?

Outside Pharmacy

Attach copy of medication label +/- recipe (if will give) **OR** include the following in the request:

- Pharmacy Name
- Pharmacy Phone Number
- Pharmacy Address
- RX # (if available)
- Any directions and/or ingredients if available.

Label Product per 2011 National P&T Minutes:

- Must enter order into BEMR with the BOP label referencing the medication name, filling pharmacy name, and statement that "patient is authorized to carry this medication"
- Cannot repackage, instead place non-BOP medication items into a clear plastic bag with the BEMR label affixed to the plastic bag to authorize self-carry.

BOP Pharmacy

Is the compound in BEMR already?

1. Go to: Reports -> Drug File
2. Make "Formulary" = ALL
3. Select the box next to "Compound" towards the bottom
4. Click "View"
5. Review report and see if desired compound is listed

Complete the **MASTER FORMULATION RECORD WORKSHEET** on the next page and submit to the BEMR Informatics team for addition to the National Drug File.

Complete the **COMPOUNDING RECORD WORKSHEET** on the following pages and store in Document Manager

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MASTER FORMULATION RECORD WORKSHEET

Name and Strength of Product:_____Quantity: _____
(# of units, volume, weights, etc.)

Intended Use:_____ Intended Route of Administration: _____

Formula:

Ingredient	Quantity	Physical Description	Solubility	Function

Compatibility/Stability Information (Literature Search):

Special Equipment, if any: _____

Calculations:

Method/Directions for Preparation:

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____

Description of Finished Product:_____

Quality Control Tests:

Beyond-Use Dating/Recommended Storage (Check one):

- ☐ **Solid and Non-Aqueous Formulations -** No later than 25% of the time remaining until the earliest ingredient's expiration date OR 6 months, whichever Is earlier
- ☐ **Aqueous Formulations** - No later than 14 days for liquid preparations when refrigerated (36°F to 46°F)
- ☐ **All other Formulations -** No later than 30 days OR duration of therapy, whichever is earlier

Packaging: _____

Labeling: _____ (Product content and auxiliary labels)

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COMPOUNDING RECORD WORKSHEET

Name of Master Formulation Record:_____ Rx#: _____

Date Compounded: _____ Preparer Name: _____

Ingredient	Amount	Manufacturer/Source	Lot #	Expiration Date

Total quantity compounded: _____

Assigned Beyond-Use Date: _____

Solid and Non-Aqueous Formulations	No later than 25% of the time remaining until the earliest ingredient's expiration date OR 6
Aqueous Formulations	No later than 14 days for liquid preparations when refrigerated (36°F to 46°F)
All other Formulations	No later than 30 days OR duration of therapy, whichever is earlier

Copy of Label:

Description of final preparation: _____

Pharmacist Verification: _____

QC Completed by: _____

Results of QC: _____

Any QC issues that arose: _____

Any reported Adverse Drug Reactions: _____

Urgent Care Cart and Kit Content

MRCs with 24 hour coverage that have a sufficient number of trained staff to perform ACLS 24 hours per day, 7 days per week may elect to stock their Urgent Care Cart with “A” list medications. Care Level III institutions with 24 hour coverage that have sufficient numbers of trained staff to perform ACLS 24 hours per day, 7 days per week wanting to stock “A” list medications must submit a request for a waiver to the Medical Director, BOP - routed through the Regional Medical Director- for approval. All other institutions will stock only medications on the “B” list. Staff using "Urgent Care Cart" supplies for resuscitation should be trained and privileged by the Clinical Director in accordance with established protocols approved by the CD.

Medication	MRCs and approved Care 3	All others
Adenosine 6 mg	A	
Amiodarone50 mg/ml	A	
Aspirin 81 mg tabs	A	B
Atropine1 mg/10ml	A	
Benztropine1mg/ml injection	A	B
D5W	A	B
Dextrose 50% injection	A	B
Digoxin 0.5 mg injection	A	
Dopamine 400 mg/5ml	A	
Epinephrine1:10000 syringe	A	
Epinephrine1:1000amps	A	
Epinephrine auto-injector 0.3	A	B
Furosemide injection	A	
Glucagon injection	A	B
Glucose paste/tabs	A	B
Haloperidol lactate inj 5mg/ml	A	B
Hydrocortisone OR methylprednisolone injection	A	B
Lactated Ringers	A	B
Lorazepam OR midazolam injection	A	B
Magnesium sulfate injection	A	
Morphine Sulfate injection	A	B
Naloxone 0.4 mg/ml injection	A	B
Nitroglycerin S.L. 0.4 mg tabs	A	B
Normal Saline	A	B
Procainamide100 mg	A	
Propranolol1 mg/ml	A	
Sodium Bicarbonate 50 mEq	A	
Sodium Chloride 0.9% injection	A	B
List continues on next page		

Other items to consider having quick access to in the Urgent Care Room, but not necessarily stored in the cart		
Medication	**MRCs and approved Care 3**	**All others**
Albuterol Inhaler	A	B
Albuterol Solution	A	B
Charcoal	A	B
Diphenhydramine 50 mg injection	A	B
Nitroglycerin 50mg/10ml	A	

High Priority Medical Conditions/Diagnoses

1. Diabetes Mellitus (high blood sugar)
2. Hypertension (high blood pressure)
3. Cardiac problems - history of heart attacks, abnormal heart rhythms, congestive heart failure, or currently having chest pain.
4. Anyone taking warfarin (Coumadin®) or other blood thinners*****
5. HIV infection
6. Cirrhosis of the liver
7. Uncontrolled asthma/COPD (emphysema) or have run out of medications*****
8. Uncontrolled seizures or have run out of seizure medicine*****
9. Any cases of active pulmonary tuberculosis*****
10. Mental health conditions such as bipolar disorder, psychotic disorders (e.g. schizophrenia); any psychiatric condition requiring antipsychotics, mood stabilizers or benzodiazepines are high risk*****
11. Hepatitis C infection - currently being treated with interferon/ribavirin, with or without protease inhibitors*****
12. Medications with withdrawal potential - chronic benzodiazepines, barbiturates, chronic narcotics, etc.*****
13. Dialysis
14. Cancer receiving active treatment
15. Antirheumatic DMARDs, non-biologic or biologic (non-urgent)*****

***** Starred conditions will be less of a priority for transfer consideration if the patients are being appropriately treated and are able to receive their medications consistently.

Therapeutic Substitution on Intake

Introduction

This document authorizes the process of therapeutic substitution by pharmacists for intake orders within the confines of the following tables. This authorization is limited to intake orders only. Any institution implementing additional agents for therapeutic substitution must obtain approval through their local P&T.

Therapeutic substitution is defined as the dispensing of a drug that is therapeutically equivalent to, but chemically different from, the drug originally prescribed by a physician or other authorized prescriber. When properly established, a therapeutic substitution program may reduce costs, prevent unnecessary non-formulary requests, increase workplace efficiency, enhance medication access, and improve inventory management.

Requirements

As noted below, each institution utilizing therapeutic substitution on intake must develop a process to notify both the original prescriber and the patient that therapeutic substitution has taken place. A description of this notification process should be placed in the local institution's P&T minutes. Copies of the institution's substitution program must be available to all providers in Health Services. Institutional Chief Pharmacists should educate applicable health care providers of this process prior to its implementation. Participation in a collaborative practice agreement (CPA) is not required for therapeutic substitution as authorized here.

NOTE: The listed equivalencies below have been approved via the National P&T Meeting and are the only ones eligible for therapeutic substitution on intake. Requests for additions to the approved list may be submitted for consideration to the National P&T Meeting via the P&T mailbox. Any other parameters desired for substitution must be discussed with the prescriber first, on a patient-by-patient basis.

Process

The following process will be adhered to by the pharmacist when performing therapeutic substitution of an intake medication order:

1. After receipt of an intake order for a non-formulary medication that is eligible for automatic therapeutic substitution, the pharmacist will write a BEMR admin note using the "Pharmacy Note" and "Pharmacy Therapeutic Interchange" designations.
2. All notes will discontinue the non-formulary drug order and add a drug order for the equivalent drug and strength found in the below equivalency tables.
    a. For pharmacists without a CPA covering the new drug in question, a TO/VO order is required. A co-signature from the prescriber selected on the original intake order is required **OR**
    b. For pharmacists with a CPA covering the new drug in question, a regular admin note will suffice with a review by the prescriber selected on the original intake order.
3. For each prescription interchanged, pharmacy staff will manually add the short sig code "PTI" in the sig field of the new order. (PTI expands to "**Pharmacy Therapeutic Interchange.**")
4. The institution should develop a mechanism to inform the patient of the therapeutic change.
5. Local P&T meetings should periodically review substitution procedures for quality assurance.

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Medication Dose Equivalency Guide by Drug Class

ACE Inhibitors	Generic Name	Dose Equivalents (mg/day)			
	Short-acting				
	Captopril	No sub	No sub	No sub	No sub
	Intermediate-acting				
	Benazepril	5	10	20	40
	Enalapril	5	10	20	40
	Moexipril	-	7.5	15	30
	Quinapril	5	10	20	40
	Ramipril	2.5	5	10	20
	Long-acting				
	Lisinopril	5	10	20	40
	Fosinopril	5	10	20	40
	Perindopril	2	4	4–8	8–16
	Trandolapril	–	1	2	4–8

Antipsychotic Long-Acting Injectables	Generic name	Approximate Dose Equivalents				
	Paliperidone ER tablet	3 mg/day		6 mg/day	9 mg/day	12 mg/day
	Paliperidone monthly IM injection	39 mg (25 mg as base)	78 mg (50 mg as base)	117 mg (75 mg as base)	156 mg (100 mg as base)	234 mg (150 mg as base)
	Paliperidone 3-month IM injection*	x	273 mg (175 mg as base)	410 mg (263 mg as base)	546 mg (350 mg as base)	819 mg (525 mg as base)
	Paliperidone 6-month IM injection ǂ	x	X	X	1,092 mg	1,560 mg
	Risperidone ER IM injection	X	25 mg every 2 weeks	37.5 mg every 2 weeks	50 mg every 2 weeks	X
	Risperidone tablet	1 mg/day	2 mg/day	3 mg/day	4 mg/day	5 mg/ day
	*Initiation of paliperidone 12-week LAI may occur only after a patient has been established on monthly paliperidone LAI for a period of at least four months, with the last two months at the same dose. ǂ Initiation of paliperidone six-month LAI may occur after the individual has been established on paliperidone (monthly) LAI for a minimum of four months or paliperidone 12-week LAI for at least one cycle (three months).					

Angiotensin Receptor Blockers	Generic name	Dose Equivalents (mg/day)	
	Candesartan	8	16
	Eprosartan	400	600
	Irbesartan	75	150
	Losartan	25	50
	Olmesartan	10	20
	Telmisartan	20	40
	Valsartan	40	80

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Benzodiazepines	Generic name	Approximate Dose Equivalents
	Alprazolam	0.25
	Chlordiazepoxide	10
	Clonazepam	0.25 - 0.5
	Diazepam	5
	Lorazepam	1
	Oxazepam	15 - 30
	triazolam	0.25
	temazepam	10

Biologic Agents (Parent Compound)	Any VA Contract FDA-approved biosimilar corresponding to the originated parent biologic as found in the FDA Purple Book (https://purplebooksearch.fda.gov).

Bupropion	Formulation	Dose Equivalent & Frequency		
	Two Pill Lines			
	Bupropion XL	N/A	150mg QD	300mg QD
	Bupropion SR	100mg BID	N/A	150mg BID
	Bupropion IR	100mg BID	75mg BID	150mg BID
	Three Pill Lines			
	Bupropion XL		150mg QD	300mg QD
	Bupropion SR	100mg BID	150mg BID	
	Bupropion IR			

Corticosteroids (inhaled)	Generic Name	Low Daily Dose	Medium Daily Dose	High Daily Dose
	Mometasone DPI	110–220 mcg	330–440 mcg	> 440 mcg
	Beclomethasone HFA	80–240 mcg	280–480 mcg	> 480 mcg
	Ciclesonide HFA	160–320 mcg	> 320–640 mcg	> 640 mcg
	Budesonide DPI	180–600 mcg	630–1200 mcg	> 1200 mcg
	Flunisolide HFA	320 mcg	> 320–640 mcg	> 640 mcg
	Fluticasone HFA	88–264 mcg	> 264–440 mcg	> 440 mcg
	Fluticasone DPI	100–300 mcg	> 300–500 mcg	> 500 mcg

Corticosteroids (nasal)	Generic Name	Dose (*each nostril)*
	Fluticasone propionate	2 sprays daily
	Fluticasone furoate	2 sprays daily
	Beclomethasone	1–2 sprays BID
	Budesonide	1–4 sprays daily
	Ciclesonide	2 sprays daily
	Flunisolide	2 sprays BID/TID
	Mometasone	2 sprays daily
	Triamcinolone	1–2 sprays daily

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Corticosteroids (topical)	Potency	Generic Name	Dosage Form	Strength (%)
	Super-high potency (group 1)	Betamethasone dipropionate augmented	Lotion, gel	0.05
			Ointment, lotion, gel	
		Clobetasol propionate	Cream, cream (emollient base), gel (scalp), ointment, shampoo, spray aerosol, foam aerosol, solution (scalp)	0.05
		Fluocinonide	Cream	0.1
		Flurandrenolide	Tape (roll)	4 mcg/cm2
		Halobetasol propionate	Lotion, cream, ointment, foam	0.05
	High Potency (group 2)	Amcinonide	Ointment	0.1
		Betamethasone dipropionate	Ointment: cream augmented form	0.05
		Clobetasol propionate	Cream	0.025
		Desoximetasone	Cream, ointment, spray	0.25
			Gel	0.05
		Diflorasone diacetate	Ointment, cream (emollient)	0.05
		Fluocinonide	Gel, solution	0.05
			Cream, ointment	
		Halcinonide	Cream, ointment, solution	01
		Halobetasol propionate	Lotion	0.01
	High Potency (group 3)	Amcinonide	Cream, lotion	0.1
		Betamethasone dipropionate	Cream (hydrophilic emollient)	0.05
		Betamethasone valerate	Ointment	0.1
			Foam	0.12
		Desoximetasone	Cream, ointment	0.05
		Diflorasone diacetate	Cream	0.05
		Fluocinonide	Cream (aqueous emollient)	0.05
		Fluticasone propionate	Ointment	0.005
		Mometasone furoate	Ointment	0.1
		Triamcinolone acetonide	Cream, ointment	0.5

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Corticosteroids (topical) ***Continued***	Potency	Generic Name	Dosage Form	Strength (%)
	Medium potency (group 4)	Betamethasone dipropionate	Spray	0.05
		Clocortolone pivalate	Cream	0.1
		Fluocinonide acetonide	Ointment	0.025
		Flurandrenolide	Ointment	0.05
		Fluticasone propionate	Cream	0.02
		Hydrocortisone valerate	Ointment	0.2
		Mometasone furoate	Cream, lotion, solution	0.1
		Triamcinolone acetonide	Cream, ointment, dental paste	0.1
			Ointment	0.05
	Lower-mid potency (group 5)	Betamethasone dipropionate	Lotion	0.05
		Betamethasone valerate	Cream	0.1
		Desonide	Gel	0.05
			Ointment	
		Fluocinolone acetonide	Cream	0.025
		Flurandrenolide	Cream, lotion	0.05
		Fluticasone propionate	Lotion	0.05
		Hydrocortisone butyrate	Cream, lotion, ointment, solution	0.1
		Hydrocortisone probutate	Cream	0.1
		Hydrocortisone valerate	Cream	0.2
		Prednicarbate	Cream (emollient), ointment	0.1
		Triamcinolone acetonide	Lotion	0.1
			Ointment	0.025
	Low potency (group 6)	Aloclometasone dipropionate	Cream, ointment	0.05
		Betamethasone valerate	Lotion	0.1
		Desonide	Cream, lotion, foam	0.05
		Fluocinolone acetonide	Cream, solution, shampoo, oil	0.01
		Triamcinolone acetonide	Lotion	0.025
			Cream, lotion	0.025
	Lowest potency	Hydrocortisone (base, ≥ 2%)	Cream, ointment, solution	2.5
			Lotion	2
		Hydrocortisone (base <2%)	Cream	1
			Ointment, gel, lotion, spray, solution,	
			Cream, ointment	0.5
		Hydrocortisone acetate	Cream	2.5
			Cream	1
			Lotion	2

ICS/LABA (inhaled corticosteroid /long-acting beta-agonist)	Generic Name	Low Daily Dose	Medium Daily Dose	High Daily Dose
	Fluticasone propionate/ Salmeterol HFA	45/21	115/21	230/21
	Fluticasone propionate/ Salmeterol Respiclick®	55/14	113/14	232/14
	Fluticasone propionate/ Salmeterol Diskus/inhub	100/50	250/50	500/50
	Budesonide/ formoterol HFA	80/4.5	160/4.5	x
	Mometasone furoate/ formoterol	x	100/5	200/5
	Fluticasone furoate/ vilanterol	x	100/25	200/25

GLP-1 (glucagon-like peptide-1) agonists	Generic Name	Frequency	Approximate Dose Equivalents				
	Semaglutide	QW (weekly)		0.25 mg	0.5 mg	1 mg	2 mg
	Dulaglutide	QW		0.75 mg	1.5 mg	3 mg	4.5 mg
	Exenatide	QW			2 mg		
	Liraglutide	QD (daily)	0.6 mg	1.2 mg	1.8 mg		
	Lixisenatide	QD	10 mcg	20 mcg			
	Semaglutide (oral)	QD	3 mg	7 mg	14 mg		
	Exenatide	BID (twice daily)	5 mcg	10 mcg			

HMG-CoA Reductase Inhibitors (“Statins”)	Generic name	Dose Equivalents (mg/day)			
		Intensity	Low	Moderate	High
	Atorvastatin		--	10-20	40-80
	Fluvastatin		20-40	80	--
	Lovastatin		20	40-80	--
	Pitavastatin		--	1-4	--
	Pravastatin		10-20	40-80	--
	Rosuvastatin		--	5-10	20-40
	Simvastatin		10	20-40	--

SNRIs (serotonin and norepinephrine reuptake inhibitors)	Generic name	Usual starting dose (mg/day)	Usual total dose (mg/day)
	Desvenlafaxine	25 – 50	50 – 100
	Duloxetine	30 – 60	60
	Levomilnacipran	20	20 – 40
	Milnacipran	12.5	100 –200
	Venlafaxine	37.5 - 75	75 – 375
	Venlafaxine XR	37.5 - 75	75 – 225

SGLT2 (sodium-glucose cotransporter-2) inhibitors	Generic name	Initial dose (mg/day)	Maintenance dose (mg/day)
	Canagliflozin	100	300
	Dapagliflozin	5	10
	Empagliflozin	10	25
	Ertugliflozin	5	15

Naloxone Protocol & Standing Order

Indication

Naloxone is indicated for the emergency treatment of known or suspected opioid overdose presenting with symptoms of respiratory or central nervous system depression.

- Symptoms of central nervous system depression may include: unresponsive or unconscious, stuporous or dulled/slowed responsiveness, constricted or pinpoint pupils.
- Symptoms of respiratory depression may include: slow or shallow breathing, absence of breathing, choking or snoring sounds, blue lips.

These symptoms may be caused by other conditions, including cardiac arrest. Upon first encountering the situation, activate emergency response right away and if drug overdose cannot be ruled out:

- **Non-medical professionals** should immediately administer naloxone and if unconscious and unresponsive without a pulse, begin CPR.
- **Licensed medical professionals** should assess the individual, if in cardiac arrest, focus on providing high quality CPR and ask a second staff member, when one becomes present, to administer naloxone.

Note: there is minimal to no harm in administering naloxone to an individual who is not having an opioid overdose.

Formulation

Naloxone nasal spray 4mg/0.1ml, or equivalent is the product that will be purchased, stocked, and used by all FBOP employees for treatment of known or suspected opioid overdose with symptoms of respiratory or central nervous system depression. Other formulations may be stocked in Health Services for use by medical employees as determined by the FBOP National Formulary.

Administration

All FBOP employees who have successfully completed the required training are expected to administer naloxone for the treatment of known or suspected overdose.

Cautions and Contraindications

Pregnancy – Administration is permitted in pregnant females if overdose is suspected by the responder. Since administration of naloxone to the mother may cause opioid withdrawal in the fetus, medical personnel responding to the emergency must be notified of the pregnancy and administration of naloxone.

Breast feeding – It is unknown whether naloxone is excreted into human milk or the effects on a breast fed infant.

Contraindications – Allergy (hypersensitivity) to naloxone or any other ingredients.

ELIZABETE STAHL Digitally signed by ELIZABETE STAHL
Date: 2025.08.27 07:45:09 -04'00'

Step 1. Don nitrile gloves, then lay the person on his/her back to receive a dose of naloxone nasal spray.

Step 2. Remove naloxone nasal spray from the box. Peel back the tab with the circle to open the naloxone nasal spray.

Step 3. Hold the naloxone nasal spray with your thumb on the bottom of the plunger and your first and middle fingers on either side of the nozzle.

Step 4. Tilt the person's head back and provide support under the neck with your hand. Gently insert the tip of the nozzle into one nostril until your fingers on either side of the nozzle are against the bottom of the person's nose.

Step 5. Press the plunger firmly to give the dose of naloxone nasal spray.

Step 6. Remove the naloxone nasal spray from the nostril after giving the dose.

Step 7. If pulseless, start or resume CPR. If there is a pulse and breathing, move the person on their side (recovery position) after giving naloxone nasal spray.

Watch the person closely.

If the person does not respond by waking up, to voice or touch, or breathing normally, another dose may be given.

Naloxone nasal spray may be given every 2 to 3 minutes in alternating nostrils.

Repeat steps 2 through 6 using a new naloxone nasal spray to give another dose in the other nostril. Steps 2 through 6 may be repeated every 2 to 3 minutes until the person responds or emergency medical help is received.

Step 8. Place the used naloxone nasal spray(s) back into its box and return to Health Services for disposal and replacement. Health Services employees document administration in BEMR.

Standing Order

Health Services staff may dispense/distribute to appropriate staff in sufficient quantities to meet local procedures for administration to persons who are suspected of experiencing an opioid overdose.

_____ _____

Dr. Elizabete Stahl, DO — Date

Medical Director

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National Permitted Night Stock Items

Nightstock Item
NS Acetaminophen 325 MG Tablet 3 day Pack (24)
NS Acetaminophen Tablet 3 day Pack (12)
NS Acyclovir 200 mg Caps 3 day (15) Bottle
NS Acyclovir 400 MG Tablet 3 day pack (9)
NS Acyclovir 800 MG Tablet 3 day pack (15)
NS Albuterol 8.5 GM Inhaler
NS Amlodipine Tablet 3 day pack (3) 5 MG Each
NS Amoxicillin Capsule 3 day pack (9) 250 MG Bottle
NS Amoxicillin 500 MG Capsule 3 day pack (9)
NS Amoxicillin Dental pack 2GM (4 x500mg caps)
NS Apixaban 2.5mg tablet 3 day pack (6)
NS Apixaban 5mg tablet 3 day pack (6)
NS Aspirin 325 MG Tablet 1 Day pack (1)
NS Aspirin E.C. 325 MG Tablet 3 Day Pack (24)
NS Atenolol 25 MG Tablet 3 Day Pack (3)
NS Atenolol 50 MG tablet 3 day pack (3)
NS Augmentin 875/125MG Tablet 3 day Pack (6)
NS Augmentin 500mg Tablet 3 day pack (6)
NS Azithromycin 250 MGz-Pack
NS Sulfamethoxazole/Trimeth 800mg /160mg Tablet 3 day pak (6)
NS Bisacodyl 5 MG Tablet prep (4)
NS Captopril 12.5 MG Tablet 1 dose
NS Carvedilol 6.25 MG Tablet 3 Day Pack (6)
NS Carvedilol 25 MG tablet 3 day pack (6)
NS Cephalexin Capsule 3 day 250 MG Bottle
NS Cephalexin 500 MG Capsule 3 day Pack (9)
NS Cephalexin 500 MG Capsule (12) Pack
NS Ciprofloxacin 500 MG Tablet 3 Day Pack (6)
NS Clarithromycin 500 MG Tablet 3 Day Pack (6)
NS Clindamycin 300 MG Capsule 3 Day Pack (12)
NS Clindamycin 150 MG Capsule 3 Day Pack (24)
NS Clonidine 0.1 mg weekly Patch (1)
NS Clonidine 0.2 MG weekly Patch (1)
NS Clopidogrel Tablet 3 day (3) 75 MG Bottle
NS Clopidogrel 300 MG One Time Dose
NS Cortisporin otic susp 10 ml
NS Diclofenac 0.1% ophth soln (2.5 mL) Bottle
NS Dolutegravir 50mg Tablet 3 day pack (3)

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Nightstock Item
NS Doxycycline 100 MG Capsule 3 Day Pack (6)
NS Erythromycin opth oint 3.5 GM
NS Furosemide 20 MG Tablet 3 Day Pack (3)
NS Furosemide 40 MG Tablet 3 day Pack (3)
NS Gentamycin Ophth Soln 5 ML
NS Gentamycin Opth Ointment (3.5 GM) Tube
NS Glipizide 5 MG Tablet 3 day pack (6)
NS Glucose pack (10)
NS Golytely orals soln reconstit 4000 ml
NS Hydralazine 50mg Tab 3 day(6) Pack
NS Hydrochlorothiazide 25 MG Tablet 3 Day Pack (3)
NS Ibuprofen 400 MG Tablet 3 day pack (9)
NS Ibuprofen 400 MG Tablet 3 day pack (12)
NS Ibuprofen 600 MG Tablet 3 day pack (9)
NS Ibuprofen 600 MG Tablet 3 day pack (12)
NS Ibuprofen 800 MG Tablet 3 day pack (9)
NS Ibuprofen 800 MG Tablet 3 day pack (12)
NS Levetiracetam 500mg 3 days supply (12) Bottle
NS Levofloxacin 500mg Tablet 3 day Pack (3)
NS levofloxacin 750MG tablet 3 day pack (3)
NS Levonorgestrel 1.5mg tablet (1)
NS Levothyroxine 50 MCG Tablet 3 day pack (3)
NS Lisinopril 10 MG Tablet 3 Day Pack (3)
NS Lisinopril 5 MG Tablet 3 Day Pack (3)
NS Lisinopril 20 MG Tablet 3 Day Pack (3)
NS Loperamide 2 MG Capsule 3 Day Pack (6)
NS Metformin 500 MG Tablet 3 Day Pack
NS Metformin Tablet 3 day pack 1000 MG
NS Methylprednisolone 4 MG 21 Dose Pack
NS Metoprolol Tablet 50 MG 3 Day Pack (6)
NS Metoprolol 25 MG Tablet 3 Day Pack (6)
NS Metronidazole 250 MG Tablet 3 day Pack (24)
NS Metronidazole 250 MG tablet 3 day Pack (18)
NS Metronidazole 500 MG tablet 3 day pack (12)
NS metronidazole 500mg 3 day (6) pack Bottle
NS Molnupiravir 200mg Caps 1 course (2) *** Mail Order sites ONLY*
NS Milk of MMagnesia Oral susp 30 ML
NS Naproxen 500 MG Tablet 3 Day Pack (6)
NS Nirmatrelvir/ritonavir oral 1 course (2)
NS Nitrostat bottle 0.4 MG Tablet Sublingual
NS Nitrofurantoin Caps 100mg 3 day pack (6)

Nightstock Item
NS Ofloxacin 0.3% ophth soln 5 mL
NS Ondansetron 8 MG Tablets (6) Bottle
NS Oseltamivir 75 MG 5 Day Pack (10)*** Mail Order sites ONLY*
NS Penicillin 500 MG Tablet 3 day pack (12)
NS Exposure Kit (combo pack-ralt/truv) 3 day Bottle
NS Exposure Kit (combo pack-dolu/truvada 3 day) Bottle
NS Permethrin 5% cream 60 GM
NS Permethrin 1% Lotion 60 ML
NS phenazopyridine 95MG tab 2 day (12) pack
NS Phenytoin 100 MG Capsule 3 Day pack (9)
NS Phytonadione 5 MG 1 Dose
NS PREA Kit (azith/metronid Combo -1 day)
NS Prednisone 10 MG 21 Dose Pack
NS Prednisone 10 MG 48 Dose Pack
NS Prednisone 20 MG Tablet (3) 3 day pack
NS Prednisone 20MG Tablet (6) 3 day pack
NS Prednisone 5 MG 21 Dose Pack
NS Prednisone 5 MG 48 Dose Pack
NS Prednisolone Acetate 1% ophth soln 5 ml
NS Raltegravir 400 MG Tablet 3 Day Pack
NS Sulfamethoxazole/Trimeth 800mg /160mg Tablet 3 day pack (6)
NS Tenofovir/Emtricitabine 300/200MG Tablet 3 Day Pack
NS Thiamine 100 mg Tablet 3 Day Pack (3)
NS Tobramycin 0.3% ophth soln 5 ml
NS Triamcinolone dental paste 0.1% 5 gm
Items expected to be stocked as UNIT Dose due to variance in Dosing
Warfarin Tablets
Ivermectin

BOP National Formulary Part II

Refer to BEMR RX Formulary Drug File Report

Session-Based Invoice Verification

This form is utilized to assure invoice verification for session-based healthcare contractors that provide services on-site.

Contractor/Service: _____

Contract Number: _____

Health Services Administrator or Designee: _____
Signature/Date

Day	Date	Time in:	Time out:	BOP Employee Name/Title	BOP Employee Signature
Sunday					
Monday					
Tuesday					
Wednesday					
Thursday					
Friday					
Saturday					
Sunday					
Monday					
Tuesday					
Wednesday					
Thursday					
Friday					
Saturday					

1 INTRODUCTION

This Quality Assurance Plan (QAP) aligns with the requirements set forth in the Performance Work Statement (PWS) titled Comprehensive Medical Services – FCI Schuylkill It establishes a nationwide strategy for the procurement and oversight of all medical service contracts. The plan addresses a comprehensive solution to previously identified deficiencies, incorporating measurable performance standards aimed at achieving the desired outcomes related to quality and timeliness of care. It also includes standards for maintaining documentation pertinent to the performance ratings outlined in the QAP.

The plan defines the procedures and guidelines the Federal Bureau of Prisons (BOP) will follow to ensure the contractor meets the required performance standards and service levels. Additionally, it assigns responsibilities to BOP staff for conducting performance surveillance, completing performance reporting tasks, and ensuring the proper documentation is maintained to support the contractor's performance ratings.

1.1 Purpose

1.1.1 The purpose of the QAP is to describe the systematic methods used to monitor performance and identify required documentation and resources to be employed. The QAP provides a means for evaluating whether the contractor is meeting the performance standards/quality levels identified in the PWS and the contractor's quality control plan (QCP), and ensures the government pays only for the level of services received.

1.1.2 This QAP defines the roles and responsibilities of all contract administration personnel, identifies the performance objectives, defines the methodologies used to monitor and evaluate the contractor's performance, describes quality assurance documentation requirements, and describes the analysis of quality assurance monitoring results.

1.2 Performance Management Approach

1.2.1 The PWS structures the acquisition around *what* service or quality level is required, as opposed to *how* the contractor should perform the work (i.e., results, not compliance). This QAP will define the performance management approach taken by the BOP to monitor and manage the contractor's performance to ensure the expected outcomes or performance objectives communicated in the PWS are achieved. Performance management rests on developing a capability to review and analyze information generated through performance assessment. The ability to make decisions based on the analysis of performance data is the cornerstone of performance management; this analysis yields information that indicates whether expected outcomes for the project are being achieved by the contractor.

1.2.2 Performance management represents a significant shift from the more traditional quality assurance (QA) concepts in several ways. Performance management focuses on assessing whether outcomes are being achieved and to what extent. This approach migrates away from scrutiny of compliance with the processes and practices used to achieve the outcome. A performance-based approach enables the contractor to play a large role in how the work is performed, if the proposed processes are within the stated constraints. The only exceptions to process reviews are those required by law (federal, state, and local) and compelling business situations, such as safety and health. A "results" focus provides the contractor flexibility to continuously improve and innovate over the course of the contract if the critical outcomes expected are being achieved and/or the desired performance levels are being met.

1.3 Performance Management Strategy

1.3.1 The contractor is responsible for the quality of all work performed. The contractor measures that quality through the contractor's quality control (QC) plan. QC is work output, not workers, and therefore includes all work performed under this contract regardless of whether the work is performed by contractor employees or subcontractors. The contractor's QCP will set forth the staffing and procedures for self-inspecting the quality, timeliness, responsiveness, customer satisfaction, and other performance requirements in the PWS. The contractor will develop and implement a performance management system with processes to assess and report its performance to the designated government representative. The contractor's QCP will also set forth the staffing and procedures for self-inspecting the quality, timeliness, responsiveness, customer satisfaction, and other performance requirements in the PWS. This QAP enables the government to take advantage of the contractor's QCP.

2 ROLES AND RESPONSIBILITIES

2.1 The Contracting Officer (CO)

The CO is responsible for monitoring contract compliance, contract administration, and cost control, and resolving any differences between observations documented by the contracting officer's representative (COR) and the contractor.

2.2 The COR

The COR is designated in writing by the CO to act as their authorized representative to assist in administering a contract. COR limitations are contained in the written appointment letter. The COR is responsible for technical administration of the contract and ensures proper technical compliance of the contractor's performance. The COR is not empowered to make any contractual commitments or authorize any contractual changes on the government's behalf. Any changes the contractor deems may affect contract price, terms, or conditions must be referred to the CO for action.

3 IDENTIFICATION OF REQURIED PERFORMANCE STANDARDS

The QAP-related performance standards are included in Attachment 1: Performance Requirements Summary.

4 METHODOLOGIES TO MONITOR PERFORMANCE

4.1 Monitoring Techniques

To minimize the performance management burden, simplified monitoring methods shall be used by the government to evaluate contractor performance when appropriate. The primary methods of monitoring are:

- *DIRECT OBSERVATION*
- *BOP DASHBOARD*
- *PERIODIC SAMPLING*
- *REVIEW OF DOCUMENTS*

5 QUALITY ASSURANCE DOCUMENTATION

5.2 Monitoring Forms

The government's QAP monitoring, accomplished by the COR, will be reported using the monitoring form in Attachment 2. The forms, when completed, will document the government's assessment of the contractor's performance under the contract to ensure the required results are being achieved.

5.2.1 The COR will retain a copy of all completed QAP monitoring forms in a file. Upon contract completion, this file will be transferred to the contracting officer.

6 ANALYSIS OF QUALITY ASSURANCE ASSESSMENT

6.1 Determining Performance

6.1.1 The government shall use the monitoring methods cited to determine whether the performance standards have been met. If the contractor has not met the requirements, they may be asked to develop a corrective action plan to show how and by what date they intend to bring performance up to the required levels.

6.2 Reviews and Resolution

6.2.1 The CO and/or COR may require the contractor to meet with the BOP to discuss the performance of the contract. Items discussed may include:

- Monthly performance assessment data
- Issues and concerns of both parties
- Projected services
- Any corrective action
- Recommendations for improved efficiency and/or effectiveness

6.3.2 The CO and COR must coordinate and communicate with the contractor to resolve issues and concerns regarding marginal or unacceptable performance.

ATTACHMENT 1: PERFORMANCE REQUIREMENTS SUMMARY

Required Task	Performance Standard	Acceptable Quality Level	Method to Monitor Performance
Timeliness of scheduling outside/inside medical care	100%	90%	Direct observation, BOP Dashboard, periodic sampling, review of documents.
Urgent Medical/Dental appointments are scheduled within 14 days or sooner if clinically indicated	100%	90%	Direct observation, BOP Dashboard, periodic sampling, review of documents
Hospital utilized maintains a quality accreditation (i.e. JC, NCCHC, etc.)	100%	100%	Periodic sampling, review of documents.
Provide inpatient and outpatient facility services including professional services which conform to community standards and all local, state and Federal laws and regulations applicable to the delivery of health care to members of the general public.	100%	95%	Periodic sampling, review of documents.

Complete by Calendar Year: **QTR 1:** Apr 15, **QTR 2:** Jul 15, **QTR 3:** Oct 15, **QTR 4:** Jan 15

ATTACHMENT 2: SAMPLE QUALITY ASSURANCE MONITORING FORM

QUALITY ASSURANCE MONITORING FORM for CMS Contracts ONLY

REQUIRED TASK (choose one or more for the quarter)

❒ Timeliness of scheduling outside/inside medical care- **Required 90% of time**

❒ Urgent Medical/Dental appointments are scheduled within 14 days or sooner if clinically indicated- **Required 90% of time**

❒ Hospital utilized maintains a quality accreditation (i.e. Joint Commission, etc.)- **Required 100% of time**

❒ Provide inpatient and outpatient facility services including professional services which conform to community standards and all local, state and Federal laws- **Required 90% of time**

SURVEY PERIOD (Quarter/Year): _____

MONITORING METHOD (check ONE OR MORE):

❒ Direct Observation ❒ BOP Dashboard ❒ Periodic Sampling ❒Review of Documents

❒ Other_____

LEVEL OF MONITORING (required quarterly at a minimum):

❒ Monthly ❒ Quarterly ❒ Other_____

ANALYSIS OF RESULTS:

Observed Service Provider Performance Measurement Rate: _____%

Service Provider's Performance (check): ❒ Meets Standards

❒ Does Not Meet Standards

Narrative of Performance During Survey Period along with corrective action taken for NOT meeting standards:_____

_____

_____

_____

_____

PREPARED BY: _____ **DATE:** _____