www.accessdata.fda.gov/scripts/cder/daf/.

Dated: April 29, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–09005 Filed 5–2–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Information (RFI): Developing an STD Federal Action Plan

AGENCY: Office of HIV/AIDS and Infectious Disease Policy, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: To help inform the development of the Sexually Transmitted Diseases (STD) Federal Action Plan, HHS seeks input from stakeholders on what strategies can be implemented by federal agencies to improve the efficiency, effectiveness, coordination, accountability, and impact of our national response to increasing rates of STDs.

DATES: To be assured consideration, comments must be received at the address provided below, no later than 5:00 p.m. ET on June 3, 2019.

ADDRESSES: Electronic responses are strongly preferred and may be addressed to *STDPlan@hhs.gov.* Written responses should be addressed to: U.S. Department of Health and Human Services, 330 C Street SW, Room L001, Washington, DC 20024; Attention STD RFI.

FOR FURTHER INFORMATION CONTACT: Melissa Habel, MPH in the HHS Office of HIV/AIDS and Infectious Disease Policy, (202) 795–7697.

SUPPLEMENTARY INFORMATION: Rates of sexually transmitted diseases (STDs) in 2017 reached an all-time high among males and females and all racial and ethnic groups. Since 2013, reported chlamydia rates have increased 22%, gonorrhea rates 67%, syphilis rates 76%, and congenital syphilis rates 154%; the combined number of cases was 2.3 million up from 1.8 million in 2013.[1] These infections can lead to long-term health consequences such as infertility and can facilitate HIV transmission. While gonorrhea, chlamydia and syphilis infections have grown considerably over the past four years, human papillomavirus (HPV) remains the most commonly sexually transmitted infection in the U.S., affecting close to half of adults of reproductive age. HPV infections result in approximately 33,700 cases of certain types of cancer each year in the U.S.[2] Most of these cancers are preventable through the use of the HPV vaccination series. These numbers represent real people and expose hidden fragile populations who are not getting the preventive services and health care they need. While STDs affect all groups of the U.S. population, they disproportionately affect certain vulnerable groups such as pregnant women, youth ages 15–24 years, men who have sex with men, and racial and ethnic minorities. Beyond the impact on an individual's health, in 2013 it was estimated that STDs cost the U.S. health care system more than $16 billion annually, and STDs have increased dramatically since then.[3]

To respond and address the STD public health epidemic, OHAIDP in collaboration with other federal partners is leading and coordinating development of a STD Federal Action Plan. The development process for the action plan will seek input from subject matter experts, nonfederal partners and stakeholders including health care providers and systems, state, tribal, and local health departments, community-based and faith-based organizations, national professional organizations, researchers, advocates, and persons whose lives have been affected by these infections. The action plan is expected to address prevention, diagnosis, care and treatment, as well as coordination of efforts, policies, and programs throughout the federal government. It will also address stigma, discrimination, co-infections (*e.g.,* HIV and viral hepatitis), and social determinants of health.

This request for information seeks public input on how the federal government should address the rising rates of STDs and what strategies can be implemented to improve the efficiency, effectiveness, coordination, accountability, and impact of the federal response to STD prevention, care and treatment policies, services and programs. The information received will inform the STD Federal Action Plan.

Topics of interest include but are not limited to the following:

1. How should the federal government address the rising rates of STDs?

2. What strategies can be implemented by federal agencies to improve the efficiency, effectiveness, coordination, accountability, and impact of our national response to increasing rates of STDs for all priority populations?

3. What are the barriers to people getting the quality STD health services they deserve? What strategies can be implemented by federal agencies to overcome these barriers?

4. How can federal agencies influence, design and implement STD-related policies, services and programs in innovative and culturally-responsive ways for priority populations?

5. How can the federal government help to reduce STD-associated stigma and discrimination?

Dated: April 11, 2019.

Tammy R. Beckham,

Director, Office of HIV/AIDS and Infectious Disease Policy.

Footnotes

1. Centers for Disease Control and Prevention. Sexually Transmitted Disease Surveillance 2017. Atlanta: U.S: Department of Health and Human Services, 2018: Available at *https://www.cdc.gov/std/stats.*

2. Eng TR, Butler WT, editors; Institute of Medicine (US). Summary: The hidden epidemic: Confronting sexually transmitted diseases. Washington (DC): National Academy Press; 1997. p. 43.

3. Owusu-Edusei K Jr, Chesson HW, Gift TL, et al. The estimated direct medical cost of selected sexually transmitted infections in the United States, 2008. Sex Transm Dis 2013; 40(3):197–201. DOI:10.1097/OLQ.0b013e318285c6d2.

[FR Doc. 2019–09113 Filed 5–2–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[OMHA–1901–N]

Medicare Program; Administrative Law Judge Hearing Program for Medicare Claim and Entitlement Appeals; Quarterly Listing of Program Issuances—January Through March 2019

AGENCY: Office of Medicare Hearings and Appeals (OMHA), HHS.

ACTION: Notice.

SUMMARY: This quarterly notice lists the OMHA Case Processing Manual (OCPM) instructions that were published from January through March 2019. This manual standardizes the day-to-day procedures for carrying out adjudicative functions, in accordance with applicable statutes, regulations, and OMHA directives, and gives OMHA staff direction for processing appeals at the OMHA level of adjudication.

FOR FURTHER INFORMATION CONTACT: Jason Green, by telephone at (571) 777–2723, or by email at *jason.green@hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Office of Medicare Hearings and Appeals (OMHA), a staff division within the Office of the Secretary within the U.S. Department of Health and Human Services (HHS), administers the nationwide Administrative Law Judge hearing program for Medicare claim; organization, coverage, and at-risk determination; and entitlement appeals under sections 1869, 1155, 1876(c)(5)(B), 1852(g)(5), and 1860D–4(h) of the Social Security Act (the Act). OMHA ensures that Medicare beneficiaries and the providers and suppliers that furnish items or services to Medicare beneficiaries, as well as Medicare Advantage organizations (MAOs), Medicaid State agencies, and applicable plans, have a fair and impartial forum to address disagreements with Medicare coverage and payment determinations made by Medicare contractors, MAOs, or Part D plan sponsors (PDPSs), and determinations related to Medicare eligibility and entitlement, Part B late enrollment penalty, and income-related monthly adjustment amounts (IRMAA) made by the Social Security Administration (SSA).

The Medicare claim, organization determination, coverage determination, and at-risk determination appeals processes consist of four levels of administrative review, and a fifth level of review with the Federal district courts after administrative remedies under HHS regulations have been exhausted. The first two levels of review are administered by the Centers for Medicare & Medicaid Services (CMS) and conducted by Medicare contractors for claim appeals, by MAOs and an Independent Review Entity (IRE) for Part C organization determination appeals, or by PDPSs and an IRE for Part D coverage determination and at-risk determination appeals. The third level of review is administered by OMHA and conducted by Administrative Law Judges and attorney adjudicators. The fourth level of review is administered by the HHS Departmental Appeals Board (DAB) and conducted by the Medicare Appeals Council (Council). In addition, OMHA and the DAB administer the second and third levels of appeal, respectively, for Medicare eligibility, entitlement, Part B late enrollment penalty, and IRMAA reconsiderations made by SSA; a fourth level of review with the Federal district courts is available after administrative remedies within SSA and HHS have been exhausted.

Sections 1869, 1155, 1876(c)(5)(B), 1852(g)(5), and 1860D–4(h) of the Act are implemented through the regulations at 42 CFR part 405 subparts I and J; part 417, subpart Q; part 422, subpart M; part 423, subparts M and U; and part 478, subpart B. As noted above, OMHA administers the nationwide Administrative Law Judge hearing program in accordance with these statutes and applicable regulations. To help ensure nationwide consistency in that effort, OMHA established a manual, the OCPM. Through the OCPM, the OMHA Chief Administrative Law Judge establishes the day-to-day procedures for carrying out adjudicative functions, in accordance with applicable statutes, regulations, and OMHA directives. The OCPM provides direction for processing appeals at the OMHA level of adjudication for Medicare Part A and B claims; Part C organization determinations; Part D coverage determinations and at-risk determinations; and SSA eligibility and entitlement, Part B late enrollment penalty, and IRMAA determinations.

Section 1871(c) of the Act requires that the Secretary publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every three months in the **Federal Register**.

II. Format for the Quarterly Issuance Notices

This quarterly notice provides the specific updates to the OCPM that have occurred in the three-month period of January through March 2019. A hyperlink to the available chapters on the OMHA website is provided below. The OMHA website contains the most current, up-to-date chapters and revisions to chapters, and will be available earlier than we publish our quarterly notice. We believe the OMHA website provides more timely access to the current OCPM chapters for those involved in the Medicare claim; organization, coverage, and at-risk determination; and entitlement appeals processes. We also believe the website offers the public a more convenient tool for real time access to current OCPM provisions. In addition, OMHA has a listserv to which the public can subscribe to receive notification of certain updates to the OMHA website, including when new or revised OCPM chapters are posted. If accessing the OMHA website proves to be difficult, the contact person listed above can provide the information.

III. How To Use the Notice

This notice lists the OCPM chapters and subjects published during the quarter covered by the notice so the reader may determine whether any are of particular interest. The OCPM can be accessed at *https://www.hhs.gov/about/agencies/omha/the-appeals-process/case-processing-manual/index.html.*

IV. OCPM Releases for January Through March 2019

The OCPM is used by OMHA adjudicators and staff to administer the OMHA program. It offers day-to-day operating instructions, policies, and procedures based on statutes and regulations, and OMHA directives.

The following is a list and description of OCPM provisions that were issued or revised in the three-month period of January through March 2019. This information is available on our website at *https://www.hhs.gov/about/agencies/omha/the-appeals-process/case-processing-manual/index.html.*

OCPM Chapter 4: Parties

The parties to an OMHA appeal are specified by regulation and vary based on the matter presented and the Medicare Part under which the appeal arises. This newly issued chapter identifies: (1) The different parties and potential parties to an appeal; (2) when an individual or entity may enter the proceedings as a substitute party; (3) when and how a beneficiary's appeal rights may be assigned to a provider or supplier; and (4) the procedures OMHA follows when an appellant's party status is unclear. There may be multiple parties to an appeal, and an individual's or entity's party status is generally not determined by the individual's or entity's financial interest in the outcome of the appeal, unless otherwise noted in this chapter.

OCPM Chapter 7: Adjudication Time Frames, Case Prioritization, and Escalations—Section 7.4.3

This chapter was initially released on July 27, 2018, and was included in a quarterly notice published in the November 14, 2018 **Federal Register** (83 FR 56859). After the initial publication, we discovered that certain language from OMHA's existing case prioritization policy had been inadvertently omitted when the policy was transferred to the OCPM. This revision to OCPM 7.4.3 corrects this error by clarifying that, if a beneficiary is represented by another party or by the same representative as another party, OMHA treats the beneficiary's case as a Priority 3 appeal (*see* OCPM 7.4.2), unless: (1) The beneficiary is or would

be liable for the costs (other than deductibles and coinsurance) of the items or services in dispute; (2) the case involves a pre-service request for coverage; or (3) one of the exceptions in OCPM 7.4.4 applies. The error we corrected was purely administrative, and had no effect on the manner in which OMHA prioritizes appeals.

OCPM Chapter 9: Request and Correspondence Intake, Docketing, and Assignment

A number of actions may initiate (or reinitiate) proceedings at the OMHA level. This newly issued chapter provides information on where to direct appeal requests and submissions, and details the processes for docketing, acknowledging, and assigning cases. This chapter also explains when claims may be added or removed from an appeal and how to combine appeals. While this chapter deals primarily with processing appeals as paper files, it also includes guidelines for processing electronic case files in OMHA's Electronic Case Adjudication Processing Environment (ECAPE).

OCPM Chapter 19: Closing the Case—Sections 19.4.3, 19.5.1

This chapter was initially released on May 25, 2018, and was included in a quarterly notice published in the August 7, 2018 **Federal Register** (83 FR 38700). This revision to OCPM 19.4.3 clarifies that, in accordance with 42 CFR 405.1044(b) and 423.2044(b), if an adjudicator issues a consolidated decision, the adjudicator must also consolidate the administrative record and combine the appeals in the case processing system. OCPM 19.5.1 was also revised, to clarify that, when an appeal involves multiple beneficiaries, any copies of disposition documents (for example, a decision and any accompanying notices or enclosures), must be redacted to display only personally identifiable information (PII) that the recipient is entitled to receive.

Dated: April 25, 2019.

Jason M. Green,

Chief Advisor, Office of Medicare Hearings and Appeals.

[FR Doc. 2019–09008 Filed 5–2–19; 8:45 am]

BILLING CODE 4150–46–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 60 Day Information Collection: Indian Health Service Forms To Implement the Privacy Rule

AGENCY: Indian Health Service, HHS.

ACTION: Notice and request for comments. Request for extension of approval.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Indian Health Service (IHS) invites the general public to comment on the information collection titled, ''IHS Forms to Implement the Privacy Rule'' Office of Management and Budget (OMB) Control Number 0917–0030.

This previously approved information collection project was last published in the **Federal Register** (81 FR 15347) on March 22, 2016, and allowed 30 days for public comment. No public comment was received in response to the notice. This notice announces our intent to submit the collection, which expires August 31, 2019, to OMB for approval of an extension, and to solicit comments on specific aspects of the information collection. A copy of the supporting statement is available at *www.regulations.gov* (see Docket ID IHS–2016–1).

Title of Collection: 0917–0030, IHS Forms to Implement the Privacy Rule (45 CFR parts 160 & 164). *Type of Information Collection Request:* Extension of the currently approved information collection, 0917–0030, IHS Forms to Implement the Privacy Rule (45 CFR parts 160 & 164). *Form(s):* IHS–810, IHS–912–1, IHS–912–2, IHS–913, and IHS–917. *Need and Use of Information Collection:* This collection of information is made necessary by the Department of Health and Human Services Rule entitled ''Standards for Privacy of Individually Identifiable Health Information'' (Privacy Rule) (45 CFR parts 160 and 164). The Privacy Rule implements the privacy requirements of the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996, creates national standards to protect individual's personal health information, and gives patients increased access to their medical records. 45 CFR 164.508, 164.522, 164.526 and 164.528 of the Rule require the collection of information to implement these protection standards and access requirements. The IHS will continue to use the following data collection instruments to meet the information collection requirements contained in the Rule.

45 CFR 164.508: This provision generally requires covered entities to obtain or receive a valid authorization for its use or disclosure of protected health information, unless otherwise permitted or required by the Privacy Rule. (See, *e.g.,* 45 CFR 164.506 for a common exception to this general rule, which involves uses and disclosure for treatment, payment, or healthcare operations.) Individuals may initiate a written authorization permitting covered entities to release their protected health information to entities of their choosing. The form IHS–810 ''Authorization for Use or Disclosure of Protected Health Information'' is used to document an individual's authorization to use or disclose their protected health information.

45 CFR 164.522: Section 164.522(a)(1) requires a covered entity to permit individuals to request that the covered entity restrict the use and disclosure of their protected health information. The covered entity may or may not agree to the restriction, and with a limited exception, a covered entity is not required to agree to a requested restriction. 45 CFR 164.522(a)(1)(vi). The form IHS–912–1 ''Request for Restrictions(s)'' is used to document an individual's request for restriction of their protected health information, and whether the IHS agreed or disagreed with the restriction. Section 164.522(a)(2) permits a covered entity to terminate its agreement to a restriction under certain conditions. For example, termination may occur if the individual agrees to or requests the termination in writing. 45 CFR 164.522(a)(2)(i). The form IHS–912–2 ''Request for Revocation of Restriction(s)'' is used to document the individual's request, the individual's agreement, and/or the agency's decision to terminate a formerly agreed to restriction regarding the use and disclosure of protected health information.

45 CFR 164.528: This provision requires covered entities to provide an accounting of certain disclosures of protected health information made by the covered entity. See also, 45 CFR 5b.9(c). The form IHS–913 ''Request for an Accounting of Disclosures'' is used to document an individual's request for an accounting of disclosures of their protected health information and the agency's handling of the request.

45 CFR 164.526: Under this provision, individuals have a right to amend protected health information or a record about the individual in a designated