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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Chapter IV

[CMS-4183-N]

Medicare Program; Listening Session Regarding the Implementation of Certain Medicare Part D Provisions in the Comprehensive Addiction and Recovery Act of 2016 (CARA)

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of meeting.

SUMMARY: This document announces a listening session to solicit input from stakeholders regarding our implementation of section 704 of the Comprehensive Addiction and Recovery Act of 2016 (CARA), which includes provisions to permit Part D sponsors to establish drug management programs for at-risk beneficiaries under which Part D sponsors may limit such beneficiaries' access to frequently abused drugs to certain prescribers and pharmacies.

Medicare beneficiaries with Part A or Part B, advocacy groups representing Medicare beneficiaries, physicians, pharmacists, and other clinicians (particularly other lawful prescribers of controlled substances), retail pharmacies, plan sponsors, entities delegated by plan sponsors (such as pharmacy benefit managers), biopharmaceutical manufacturers, and other interested parties are invited to participate. The Listening Session will be held via teleconference and is open to the public.

DATES: Meeting Date: The Listening Session announced in this document will be held via teleconference on Monday, November 14, 2016 from 1 pm to 4 pm, Eastern Standard Time (e.s.t.).

Deadline for Submitting a Request for Special Accommodations: Individuals planning to participate in the teleconference who have a condition that requires special assistance or accommodations are asked to submit their requests as specified in the **ADDRESSES** section of this document no later than 5:00 p.m., e.s.t Tuesday, November 1, 2016.

Deadline for Meeting Registration: Individuals may register online at https://www.cms.gov/Outreach-and-Education/training/CTEO/Upcoming_Current_events.html. or by phone by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this document by 1 p.m. e.s.t., Monday, November 14, 2016.

Deadline for Submission of Written Comments or Statements: Written comments or statements on the topics listed in section II.A. of this document may be sent via mail or electronically to the address specified in the **ADDRESSES** section of this document and must be received by 5 pm e.s.t., Friday, December 2, 2016.

ADDRESSES: Meeting Location: The Listening Session will be held via teleconference only.

Meeting Registration: Persons interested in participating in the teleconference must register by completing the online registration. Online registration is available via the CMS Compliance Training, Education & Outreach - Upcoming/Current Events website: https://www.cms.gov/Outreach-and-Education/training/CTEO/Upcoming_Current_events.html.

Requests for Special Accommodations: Individuals who require special accommodations should send a request via email to CTEO@cms.hhs.gov.

Written Comments or Statements: Any interested party may send written comments or statements by mail to Attn: Chad Buskirk, Centers for Medicare & Medicaid Services, Mail Stop C1-24-23, 7500 Security Boulevard, Baltimore, MD 21244-1850 or by email to PARTDPOLICY@cms.hhs.gov.

FOR FURTHER INFORMATION CONTACT: Chad Buskirk, 410-786-1630. News Media Representatives must contact our Public Affairs Office at (202) 690-6145.

SUPPLEMENTARY INFORMATION:

I. Background

Section 704 of the Comprehensive Addiction and Recovery Act of 2016 (CARA) (Pub. L. 114-198) includes provisions to permit Part D sponsors to establish drug management programs for at-risk beneficiaries under which Part D sponsors may limit such beneficiaries' access to frequently abused drugs to certain prescribers and pharmacies. Section 704(g)(2)(A) of CARA requires the Secretary of Health and Human Services to convene stakeholders for input regarding specific topics in sufficient time for the Secretary to take such input into account in promulgating regulations to implement the relevant provisions. Stakeholders include Medicare beneficiaries with Part A or Part B, advocacy groups representing Medicare beneficiaries, physicians, pharmacists, and other clinicians (particularly other lawful prescribers of controlled substances), retail pharmacies, plan sponsors, entities delegated by plan sponsors (such as pharmacy benefit managers), and biopharmaceutical manufacturers.

II. Listening Session Topics and Format

A. Listening Session Topics

Section 704 of CARA is the basis for the listening session and provides the information for which we are soliciting stakeholder input. The first topic is found in section 704(a) of CARA and the nine other topics are from the listing in section 704(g)(2)(B) of CARA. Therefore, we are soliciting feedback from stakeholders and other interested parties on the following 10 topics:

- The clinical guidelines that indicate misuse or abuse of frequently abused drugs.

Section 704(a) of CARA refers to such clinical guidelines and requires the Secretary to develop such guidelines in consultation with Part D sponsors and other stakeholders.

- The anticipated impact of drug management programs for at-risk beneficiaries under section 1860D-4(c)(5) of the Social Security Act (the Act) on cost-sharing and ensuring accessibility to prescription drugs for enrollees in prescription drug plans (PDPs), and MA-PD plans who are at-risk beneficiaries for prescription drug abuse (as defined in section 1860D-4(c)(5)(C) of the Act).

- The use of an expedited appeals process under which such an enrollee may appeal the enrollee's identification as an at-risk beneficiary for prescription drug abuse (similar to the processes established under the Medicare Advantage program that allow an automatic escalation to external review of claims submitted under Part C).

- The types of enrollees that should be treated as exempted individuals, as described in section 1860D-4(c)(5)(C)(ii) of the Act.

- The manner in which terms and definitions should be applied, such as the use of clinical appropriateness in determining whether an enrollee is an at-risk beneficiary for prescription drug abuse as defined in section 1860D-4(c)(5)(C) of Act.

- The information to be included in the notices described in section 1860D-4(c)(5)(B) of Act and the standardization of such notices.

- The responsibility for the implementation of the program of the PDP sponsor (or Medicare Advantage organization) that establishes a drug management program for at-risk beneficiaries under section 1860D-4(c)(5) of the Act.

- Notices for plan enrollees at the point of sale that would explain why an at-risk beneficiary has been prohibited from receiving a prescription at a location outside of the designated pharmacy.
- Evidence-based prescribing guidelines for opiates.
- The sharing of claims data under Parts A and B of title XVIII of the Act with Part D sponsors.

B. Listening Session Format

Stakeholders and other interested parties will be convened by teleconference for this listening session. The session will begin with teleconference logistics and an overview of objectives for the session. The remainder of the session will be devoted to receiving input on the 10 topics specified in section II.A. of this document. Time allotted for each topic will be limited.

III. Registration Instructions

Persons interested in participating the teleconference must register by completing the on-line registration via the CMS Compliance Training, Education & Outreach - Upcoming/Current Events website: https://www.cms.gov/Outreach-and-Education/training/CTEO/Upcoming_Current_events.html by the deadline specified in the DATES section of this document. You will receive a registration confirmation with the dial-in information to participate in the listening session.

Individuals requiring special accommodations should refer to the **DATES** and **ADDRESSES** section of this document.

Dated: October 7, 2016.

Andrew M. Slavitt,

Acting Administrator,

Centers for Medicare & Medicaid Services.

BILLING CODE: 4120-01-P

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