Sec. 704 CARA Stakeholder Agenda

November 14, 2016, 1-4 PM EST

Welcome / Introduction (5 min)

Section 704 Overview (5 min)

Discussion of topics in order listed below (165 min, approx. 15 min per topic)

	Statutory Topic	Discussion Questions
1.	Developing clinical guidelines that indicate misuse of frequently abused drugs.	• Besides opioids, what other frequently abused scheduled drugs should be considered? • What are suggestions for developing the clinical guidelines for opioids and other considered frequently abused drugs? • What should be considered sufficient clinical contact by the plans with providers who have prescribed frequently abused drugs regarding whether the prescribed drugs are appropriate for the at-risk beneficiary? • What are the standards for terminating a beneficiary's at-risk identification and/or maximum time period to be considered at-risk?
2.	The use of evidence-based prescribing guidelines for opiates.	• What are the prescribing guidelines that CMS should consider?
3.	Assessing the impact of drug management programs for at-risk beneficiaries on cost-sharing and accessibility	• What type of existing beneficiary education should be appropriate for the Secretary to provide with respect to drug management programs? • What types of existing public health resources are there for addressing prescription drug abuse?

	Statutory Topic	Discussion Questions
	to prescription drugs for enrollees who are considered at-risk.	• What type of data should be supplied to CMS for the purpose of identifying patterns of prescription drug utilization? • What should be considered reasonable provider/pharmacy access standards for beneficiaries with regard to geographic location, cost-sharing impact, etc.? • What should be the exception criteria to a change in a beneficiary's provider and/or pharmacy choices?
4.	How should the appeals process be used so that the enrollee may appeal or contest being identified as an at-risk beneficiary for prescription drug abuse?	• How should beneficiary complaints related to a drug management program fit into existing Part D appeals and grievance processes? • What are the advantages and disadvantages of providing for automatic escalation of beneficiary appeals related to a drug management program to an independent review entity?
5.	Which types of enrollees should be exempt from being considered at-risk (hospice and long-term care enrollees are already excluded)?	• What other types of exemptions should be deemed necessary by the Secretary (by frequently abused drug)?
6.	How should terms and definitions be applied, such as the use of clinical appropriateness in determining whether an enrollee is an at-risk beneficiary for prescription drug abuse?	• See statutory topic.

	Statutory Topic	Discussion Questions
7.	What information should be included in the notices sent to the at-risk beneficiary?	• When and how is it best to notify the dual-eligible at-risk beneficiary of ineligibility for the special enrollment period (SEP) for dual-eligible individuals? • What exceptions should there be for an expedited 2nd notice to the at-risk beneficiary when there is significant drug diversion that may give cause for an early "lock-in"?
8.	Explanation of point-of-sale notices to enrollees for why the at-risk beneficiary is prohibited from receiving a prescription outside of the designated pharmacy.	• What are the key components for the point-of-sale notices?
9.	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.	• What are the key responsibilities for Part D sponsors to develop an unbiased, neutral drug management program in Part D?
10.	Sharing claims data from Part A and B with Part D sponsors.	• What data is needed, how could Part D sponsors use the data, and could the data be used to improve other areas of the program (such as appeals)?

	Statutory Topic	Discussion Questions
		• What are the concerns with providing this data to stand-alone Part D sponsors? • What other data could Part D sponsors supply to CMS for the purpose of identifying patterns of prescription drug abuse?

Closing Remarks (5 min)