Overview of Section 704 of the Comprehensive Addiction and Recovery Act of 2016 ("CARA")

Chad Buskirk

Lisa Thorpe, Esquire

Division of Part D Policy, Medicare Drug Benefit and C&D Data Group, CMS

September 8, 2016

CARA Overview

- Became law on July 22, 2016
- Effective on or after January 1, 2019
- Requires rulemaking
- Allows Part D plan sponsors to establish a drug management program which may limit “at-risk” beneficiaries’ access to
  - A controlled substance that CMS determines to be frequently abused or diverted (FAD)
  - Selected prescriber(s)
  - Selected pharmacy(ies)

Who is Considered "At-Risk"

- Beneficiary identified through the use of clinical guidelines that indicate misuse or abuse of "frequently abused drugs" (FAD)
- Beneficiary identified as at-risk in most recent Part D plan and identification not terminated
- Not "exempted" because receiving hospice services, resident of an LTC or other facility which dispenses FAD through a single pharmacy, or in a category CMS elects to treat as exempted

Requirements

- Part D sponsors may not limit access until they have
  - Provided beneficiary with initial notice
  - Verified with the beneficiary's providers that beneficiary is "at-risk"

Initial Notice

- Explains that the PDP sponsor has identified the beneficiary as potentially being “at risk”
- Provides information and resources about prescription drug abuse
- Includes organizations that can assist beneficiary through the drug management program
- Requests beneficiary preferences for prescribers and pharmacies
- Appeal rights
- How to contact the Part D sponsor

2nd Notice

- Sent no less than 30 days after initial notice
- Explains Part D sponsor has identified beneficiary as "at-risk"
- Beneficiary is subject to requirements of the Part D sponsors drug management program
- Prescribers and pharmacies selected
- Requests beneficiary preferences for prescribers and pharmacies (if beneficiary has not already submitted)
- Appeal rights
- How to contact the Part D sponsor

Point-of-Sale Notice

- Provided to an at-risk beneficiary when he/she attempts to purchase a “frequently abused drug” at a non-selected pharmacy
- Explains why beneficiary cannot obtain drug under his/her Part D plan

Selection of Prescriber and Pharmacy

- Part D sponsor shall select prescriber and pharmacy from at-risk beneficiary's list of preferences
- Part D sponsor must notify the prescriber and pharmacy before they are selected
- Part D sponsor may change selection of either prescriber or pharmacy if they determine selection contributes to drug abuse or diversion
  - Part D sponsor shall provide beneficiary 30-days' written notice and rationale

Reasonable Access

- Part D sponsor will consider the following to ensure reasonable access
  - Geographic location/multiple residences
  - Beneficiary preference
  - Cost-sharing impact
  - Reasonable travel time
  - Emergency services/natural disasters

Stakeholder Meeting

- Held no later than January 1, 2017
- Announced via Federal Register Notice, HPMS memo, and some direct outreach to required attendee groups
- Encourage early input on specific topics
  - Anticipated impact on cost-sharing and ensuring accessibility
  - Appeals process that will be used by impacted beneficiaries
  - Types of enrollees who should be treated as exempted individuals
  - How should clinical appropriateness be used in determining an at-risk beneficiary
  - Information that should be included in the beneficiary notices
  - Responsibilities of Part D sponsors implementing this program
  - Point-of-sale notices explaining why an at-risk beneficiary has been prohibited from obtaining frequently abused drugs (FAD)
  - Sharing of Part A/B claims data with Part D sponsors

Questions?