Opioid Strategy Layout

Required File Format = Microsoft® Word

Filename extension should be ".doc" or ".docx"

This submission document should contain a summary of your organization's comprehensive strategy to combat the opioid crisis. Provide information on your current strategy and note changes or new strategy to be implemented for the upcoming contract year. If the same strategy applies to multiple contracts, only one document needs to be uploaded and the applicable contracts may be associated to the document during the upload process. This applies to all organizations offering a Part D benefit, including PACE and Employer Groups. CMS will utilize information submitted through this process to assist in the modification of existing Part D policy and/or development of new policy to help combat the opioid crisis. We may also synthesize information and publish "best practices." Any information made publicly available will be summarized and not attributed to a specific organization.

The strategy document should be divided into sections as outlined below. Examples of information to be included in the sections are recommendations only. Sponsors are not required to address each example and should include any additional information related to these areas. The submissions will not be subject to an approval process and modifications or resubmissions will not be requested by CMS.

- P&T Opioid Formulary Design Approach – What formulary placement strategies are utilized? For example, placing certain opioids in non-preferred versus preferred tiers, inclusion of alternatives to treat pain in preferred tiers, and formulary considerations of abuse-deterrent opioids. What utilization management techniques are applied to opioids, and are there differences in how these are applied based on the specific opioid? How are quantity limits determined? Do prior authorization or step therapy requirements result in preferring certain opioids over others, or non-opioids versus opioids? What clinical guidelines or other sources are utilized in the formulary development process?
- Concurrent Drug Utilization Review (DUR) – How are the morphine milligram equivalents (MME) hard and/or soft edits developed? How is the effectiveness of these edits monitored and what adjustments are made as a result? What additional concurrent DUR editing is performed on opioids? Are the edits hard or soft edits? Are opioid prescriptions limited to days supplies or unit restrictions, and if so, what is utilized and how are they developed? What challenges have you encountered in implementing concurrent DUR?
- Medication Therapy Management (MTM) Program – Are opioids explicitly addressed in your MTM program? Do you offer MTM services to at-risk beneficiaries, who do not otherwise qualify for MTM? If so, what kind of MTM services or interventions do you offer?
- Retrospective DUR Strategies – Do you have a drug management program? If not, why not and what program do you have instead to address opioid overutilization? (Please describe in detail and include the impacted beneficiary population size). If so, please describe the overall approach of your drug management program. Please include in your description 1) how you apply the clinical guidelines/OMS criteria to your beneficiary population; 2) whether you use a wait and see approach to case management, and if so, do you always use it or do you address certain cases more immediately by contacting the prescribers telephonically?; 3) how you

handle at-risk beneficiaries who continue to meet the clinical guidelines/OMS criteria; 4) your experience with making exceptions to at-risk beneficiary preferences and providing reasonable access to beneficiaries, and beneficiary appeals; 5) how you approach potential and at-risk beneficiaries who change plans; and 6) how you have addressed your program with your pharmacy and provider (if applicable) network.

- Fraud, Waste, and Abuse (FWA) Programs – Please describe any FWA programs or activities specific to opioids and the effectiveness of these programs.
- Medication-Assisted Treatment (MAT) Access Initiatives – What formulary and benefit designs are incorporated to promote appropriate access to Part D MAT? What activities does your organization perform to promote and/or monitor adherence to MAT? What types of edits are drugs indicated for MAT subject to at point-of-sale?
- Overuse Prevention – Describe what strategies, if any, your organization has in place with respect to overdose prevention, outside of formulary placement. For example, to increase access to overdose reversal drugs; conduct education with doctors, pharmacies, and beneficiaries; use of pain treatment plans; promote the use of prescription drug monitoring program (PDMP) databases; and/or medication disposal.
- Use of Medicare Advantage (MA) Data to Support Opioid Crisis Efforts (MA Plans) – How is MA data utilized in the identification of opioid utilization? How is data utilized in the outreach and management of overutilization? What coordination is done between the health and drug benefits to address overutilization? What care management interventions are provided to enrollees using high dosage opioids?
- Commercial Efforts to Combat the Opioid Crisis – Please describe any programs, initiatives, or other efforts that you have in place for your commercial lines of business. Have these efforts been successful? Please describe any Part D policy barriers that are in place that would prevent you from implementing these programs in Part D.
- Lessons Learned or Outcomes Data – Describe outcomes of your strategy, lessons learned, or best practices.
- Other