Opioid Strategy Layout

Required File Format = Microsoft® Word. Filename extension should be ".doc" or ".docx"

This 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 in or new strategies to be implemented for the upcoming contract year. If the same strategy applies to multiple contracts, only one document needs to be uploaded via the Health Plan Management System 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 Group Waiver Plans. CMS may utilize information submitted through this process to assist in the modification of existing Part D policy and/or the development of new policy to help combat the opioid crisis. We may also synthesize information and publish "best practices" for Part D Sponsors. 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. Sponsors should provide all relevant information for each section. If there is no relevant information for a section, sponsors should indicate "N/A" in that section. The questions in each section are intended only as helpful prompts and none require a specific response. The submissions will not be subject to an approval process and modifications or resubmissions will not be requested by CMS.

- P&T Committee Formulary Design Approach for Opioids – 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 resources are utilized in the formulary development process?
- Concurrent Drug Utilization Review (DUR) Strategies – What concurrent DUR opioid safety edits are in place? For example, soft or hard edits based on morphine milligram equivalents (MME), days' supply/unit restrictions, or therapeutic duplication? How are the edit specifications developed? How do you identify patients for whom the prescriptions are appropriate (e.g., beneficiaries with a cancer diagnosis) in order to exclude them from further edits? How is the effectiveness of these edits and their impact on complaints and appeal requests monitored, and what adjustments are made as a result? How do you educate dispensing pharmacists about such edits? What strategies do you use to reduce confusion and retain dispensing pharmacist engagement and alertness across the spectrum of edits? What challenges have you encountered in this area?
- 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 Drug Utilization Review (DUR) Strategies – Do you have a drug management program? If no, why? Please identify perceived barriers and challenges to implementing such programming and whether or not the same applies to both stand-alone prescription drug plans (PDPs) and Medicare Advantage Prescription Drug plans (MA-PDs). What programs do you have in place instead to address opioid overutilization? Please describe in detail and include the impacted beneficiary population size. If you do have a drug management program, in place, please describe the overall approach for the program. Please include in

your description 1) how you apply the clinical guidelines/Overutilization Monitoring System (OMS) criteria to your beneficiary population, such as applying the minimum criteria more frequently or applying the supplemental criteria; 2) your experience with identifying beneficiaries who are exempt and those who only meet the criteria because they are being cared for by a group practice and/or chain pharmacy; 3) 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?; 4) how you handle at-risk beneficiaries who continue to meet the clinical guidelines/OMS criteria; 5) your experience with making exceptions to at-risk beneficiary preferences and providing reasonable access to beneficiaries, and beneficiary appeals; 6) how you approach at-risk and potentially at-risk beneficiaries who change plans, and your experience in obtaining and transferring case management information from plan to plan; 7) how you educate your pharmacy and provider network (if applicable) about your program; and 8) what elements or metrics do you track beyond what is reported through OMS about the outcome of the program. What are best practices in conducting case management with prescribers of potentially at-risk beneficiaries? And can you identify any additional best practices when prescribers are not responsive to case management? How often does this happen?

- Fraud, Waste, and Abuse (FWA) Programs – Please describe any FWA programs or activities specific to opioids and the effectiveness of these programs. How do these programs differ from FWA programs not specific to opioids? If your organization is using advanced analytic techniques (e.g., using predictive modeling to identify members more likely to exceed recommended MMEs), have you found them to be effective? What strategies do you employ to monitor prescribing patterns to identify outlier prescribers?
- Medication-Assisted Treatment (MAT) Access Initiatives – What formulary and benefit designs are incorporated to promote appropriate access to MAT? What activities does your organization perform to promote and/or monitor adherence to MAT? What types of edits are drugs used in MAT subject to at point-of-sale? Do you leverage the drug management program or other touch points to promote MAT where needed? What challenges have you identified for beneficiary access to MAT? What processes have you implemented to reduce these barriers?
- Overdose 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 opioid reversal agents; conduct education initiatives with doctors, pharmacies, and beneficiaries; use of pain treatment plans; promoting the use of prescription drug monitoring program (PDMP) databases; and/or medication disposal. Which strategies or programs have you found to be most effective?
- Medicare Advantage (MA) Efforts to Address the Opioid Crisis (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? What benefits, if any, are being offered that are targeted for opioid addiction and/or pain management? What barriers do MA plans face in addressing the opioid crisis, or in offering targeted benefits to meet the needs of members with significant pain and/or facing opioid addiction?
- Engagement of Medicare Advantage Special Needs Plans (SNPs) to treat beneficiaries with opioid addiction – Has your organization considered offering either an MA local Special Needs Plan (SNP) or a SNP Regional Preferred Provider Organization (RPPO) to treat enrollees with opioid addiction? Does your organization see any problems with using a SNP to treat beneficiaries with opioid addiction? Do you have any recommendations for CMS to improve MA SNPs to better serve Medicare

enrollees with opioid addiction?

- Commercial, Medicaid, or Health Insurance Marketplace Efforts to Combat the Opioid Crisis – Please describe any programs, initiatives, or other efforts that you have in place for your other lines of business. How do state pharmacy laws influence your overutilization efforts? What state requirements, if any, have you found to be effective in reducing opioid overutilization in 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.
- Education and Outreach – Describe your efforts to educate and prepare pharmacists, prescribers, and beneficiaries on your opioid strategies. Have some efforts been more successful than others?
- Lessons Learned or Outcomes Data – Describe outcomes of your strategy, lessons learned, or best practices.
- Other–Use this section to provide any other information related to your efforts to combat opioid overutilization not captured in an earlier section.