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Thursday, March 26, 2020

Dockets Management Staff

Centers for Medicare & Medicaid Services

U.S. Department of Health and Human Services

7500 Security Boulevard

Baltimore, Maryland 21244

**RE:** Comment on the Medicare and Medicaid Programs: Contract Year 2021 and 2022 Policy and Technical Changes Proposed Rule (CMS-2020-0010) – **Information on the Safe Disposal of Prescription Drugs (§ 422.111; p. 87-105)**

Dear Administrator Verma:

As participants in the Collaborative for Effective Prescription Opioid Policies (CEPOP;

www.CEPOPonline.org), we are writing in response responds to the public comment opportunity around the Center for Medicare & Medicaid Services’ (CMS) proposed rule for Contract Years 2021 and 2022 for the Medicare Advantage (MA) and Part D programs. Specifically, we wish to provide the agency with our perspective on implementation of Section 6103 of the SUPPORT for Patients and Communities Act (SUPPORT Act), set to take effect January 1, 2021.[[1]](#endnote-1) The comments below pertain specifically to §422.111 of the proposed rule and anticipated implementation.

As concerned stakeholders committed to turning the tide of the opioid epidemic, we urge CMS to further investigate and implement at-home disposal technologies to rid of unused and unwanted prescription drugs. In particular, efforts should be made to ensure these products are evidence-based and render discarded dosage units non-retrievable for misuse, abuse and diversion in order to protect beneficiaries themselves as well as their families.

CEPOP is a diverse group of more than 80 stakeholders – interested in the manufacture, distribution, appropriate use of opioid and non-opioid medications, non-pharmacologic interventions, medication-assisted treatment and disposal of unused and unwanted prescription drugs – who have joined together to work toward a comprehensive and balanced policy strategy to prevent misuse, abuse, diversion and promote treatment and recovery options. We support effective programs, strategies and balanced policies to help prevent prescription painkiller misuse and overdose while ensuring patients' access to safe effective pain treatment.

In the last several years, CEPOP has responded to the evolution of the opioid epidemic by evolving itself. Recognizing the need for efforts to augment biannual *National Drug Takeback Days*, CEPOP has worked to build out a *Safe Disposal and Anti-Diversion Working Group* that has developed a robust agenda tackling some of the most complex components of a coordinated epidemic response. While takeback days play an important role in removing unused and unwanted prescription drugs from the home, these are not accessible to all Medicare beneficiaries. Furthermore, unforeseen circumstances such as our current COVID-19 pandemic have caused for the cancellation of scheduled events. In lieu of these resources, efforts should be made to make accessible other resources that have been proven to easily and effectively mitigate risks of leftover opioids. In July 2017, CEPOP hosted a briefing on Capitol Hill focused specifically on “Preventing Diversion of Opioid Medications: Safe Storage and Disposal Strategies.”.[[2]](#endnote-2) As part of that effort, we were pleased to have national leaders speak to the success of these supporting interventions and impacts on patient safety and public health. Congressional leaders, including Representatives Susan Brooks, Ann McLane Kuster, and Bill Keating all participated and voiced support around evidence-based at-home disposal opportunities.

Commensurate with CEPOP’s focus on a comprehensive response to drug disposal and takeback programs, federal agency partners have begun to recognize the evidence supporting these interventions. The President’s Commission on Combatting Drug Addiction and the Opioid Crisis referenced at-home disposal in its final report, issued in November 2017.[[3]](#endnote-3) Recommendation #17 of the report specifically encourages the utilization of at-home disposal to augment existing takeback efforts, “Drug deactivation bags would be particularly useful in rural areas where an authorized collector may not be nearby. The use of such bags would complement Take Back Day events and give consumers more options.”[[4]](#endnote-4)

This recommendation was critically important following the release of a Government Accountability Office report (GAO-18-25) a month prior that a mere 2.49% of all eligible entities made available to beneficiaries disposal bins for unused prescription drugs. At that time, less than 5% of eligible pharmacy sites in 44 states were authorized collection sites.[[5]](#endnote-5)

Research from highly esteemed academic medical centers including the University of Michigan[[6]](#endnote-6) and The Ohio State University[[7]](#endnote-7) highlights another key component of at-home drug disposal technologies: they change behavior. Beyond ensuring the effectiveness of the products available to beneficiaries, it’s almost tantamount that the information and interventions made available to them are utilized. Researchers from the University of Michigan write in *JAMA Surgery* that study respondents were 3.8-times more likely to dispose of unused and unwanted opioids as compared to the control arm receiving usual care. More than half of those receiving an at-home disposal technology (57.1%) self-reported opioid disposal compared to a mere 28.6% not receiving the intervention. Similar results were presented in *JAMA Pediatrics* in which more than 85% of participants receiving an at-home disposal technology properly disposed of prescription opioids compared to the only two-thirds that did so based upon educational materials.

Recently, the U.S. Food and Drug Administration has announced changes to their at-home drug disposal webpage for products on the “non-flush list.” [[8]](#endnote-8) The added reference indicates, “Other technologies which provide additional options for disposing of medicines have been developed.”

Efforts to promote evidence-based at-home drug disposal is already occurring on the state-level, led by New Jersey. In January, the state enacted “Charlie’s Law” (New Jersey P.L.2019, c.509) that requires pharmacists to offer patients written and oral information around appropriate disposal of unused and unwanted medications in addition to a physical disposal method. The important distinction here is that the state intends to change behavior beyond simple education but also providing a physical tool to remove unused and unwanted products from the home. We urge CMS to follow this effort and provide beneficiaries with evidence-based interventions to support the overarching intention of the SUPPORT Act provisions and the educational components stemming from beneficiary outreach.

Ultimately, however, we encourage the agency to ensure alignment of the MA/Part D educational program with existing statute promulgated by the Drug Enforcement Administration (DEA). The DEAs controlled substance authorities clearly identify that disposal of unused and unwanted prescription drugs must be conducted in a way that renders products non-retrievable in which the active ingredients are “unavailable and unusable for all practical purposes.”[[9]](#endnote-9). Both the SUPPORT Act (P.L. 115-271, Section 3032(a)(4)(B)) and Charlie’s Law (New Jersey P.L. 2019, c. 509) rely on this standard. We encourage CMS to do the same. Compliance with 21 CFR §1300.05 will ensure that all controlled substance dosage units removed from households will be rendered non-retrievable and are no longer available for misuse, abuse or diversion by beneficiaries, family, friends or others.

As we all recognize, the outcomes of this program will save lives and avoid the unnecessary transition of unused and unwanted prescription opioids into dosage units that are misused, abused or diverted. The evidence presented above indicates as much and substantiates the need for all evidence-based interventions to be made available to Medicare beneficiaries.

Thank you for your consideration of our views. CEPOP, and the undersigned organizations, stand ready to assist the agency as it looks to develop and implement this life-saving initiative.

Sincerely,

[INSERT STAKEHOLDERS]

cc: Kimberly Brandt, *Principal Deputy Administrator for Policy and Operations*

Jeffrey A. Kelman, MD, *Chief Medical Officer, Center for Medicare*

Amy Larrick Chavez-Valdez, *Director, Medicare Drug Benefit and C & D Data Group, Center for Medicare*

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1. <https://www.federalregister.gov/documents/2020/02/18/2020-02085/medicare-and-medicaid-programs-contract-year-2021-and-2022-policy-and-technical-changes-to-the> [↑](#endnote-ref-1)
2. <https://cepoponline.org/actionitems/cepop-holds-congressional-briefing-preventing-diversion-opioid-medications/> [↑](#endnote-ref-2)
3. <https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf> [↑](#endnote-ref-3)
4. *Id* [↑](#endnote-ref-4)
5. <https://www.gao.gov/assets/690/687719.pdf> [↑](#endnote-ref-5)
6. <https://jamanetwork.com/journals/jamasurgery/article-abstract/2729448> [↑](#endnote-ref-6)
7. <https://jamanetwork.com/journals/jamapediatrics/article-abstract/2735686> [↑](#endnote-ref-7)
8. <https://www.fda.gov/drugs/disposal-unused-medicines-what-you-should-know/drug-disposal-dispose-non-flush-list-medicine-trash> [↑](#endnote-ref-8)
9. 21 CFR §1300.05 [↑](#endnote-ref-9)