Abuse Deterrent Coalition

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January 12, 2018

Seema Verma
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4182-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: CMS-4182-P

Dear Administrator Verma,

The undersigned members of the Abuse Deterrent Coalition (ADC) offer the following comments for consideration on Docket No. CMS-2017-0157, "Medicare Program: Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program."

The ADC is a forum of abuse-deterrent formulation technology innovators, patient and issue associations and pharmaceutical manufacturers created to educate the public, policy makers and related regulatory agencies on the importance of abuse-deterrent (AD) opioids technologies utilized in the fight against prescription drug abuse. The Coalition serves as a unified voice for legislative and regulatory initiatives that support the required use of AD technologies for prescription drugs that have a high potential for abuse.

Addressing and curtailing the abuse of prescription opioids is a multi-model process requiring action from multiple stakeholders to successfully reduce the abuse of prescription opioids. For example, the Opioid Action Plan developed by the U.S. Food and Drug Administration (FDA) in February 2016 appropriately focuses on both patients and the community at large to ensure balanced access to effective pain medications, while reducing the societal burden of opioid abuse, misuse and diversion.

The President's Commission on Combating Drug Addiction and the Opioid Crisis also recognizes the value AD opioids can provide as an alternative to non-AD opioid medications.[1] In addition to effective treatment of the negative consequences of opioid abuse (i.e., Naloxone for overdose and medication assisted therapy [MAT] for addiction), supporting the development and increasing the availability of AD opioids represents a critical component of drug abuse prevention efforts.

In administering Part D, CMS has a tremendous opportunity to add to the effort to reduce and deter the abuse of prescription opioids. The agency's own statistics show that opioid use by Medicare beneficiaries is ubiquitous: one in every three Medicare Part D beneficiaries received at least one prescription opioid in 2016,[2] and 500,000 beneficiaries received high amounts of opioids through Medicare Part D for extended periods of time.[3] In the proposed rule, CMS has estimated that more than 319,000 beneficiaries could be potentially at-risk for opioid overutilization under varying scenarios.[4] The Department of Health & Human Services Office of the Inspector General (HHS OIG) also has acknowledged that although beneficiaries may receive opioids for legitimate purposes, the high number of at-risk beneficiaries appropriately raises concern.[5]

AD opioids are a currently available tool specifically designed to help reduce the risks associated with abuse, misuse and diversion of prescription opioids. Moreover, AD opioids not only deter abuse, misuse and diversion of the drug by patients for whom they are prescribed – in this case, Medicare beneficiaries – but also by others who may have access to the products in the home (family members, hired workers, etc.). AD opioids offer the promise of a significant public health benefit by deterring the illegal diversion of opioids.[6] Deterrence (prevention) of prescription opioid abuse is a more cost-effective approach to

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[1] Available at: https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.
[2] Department of Health and Human Services Office of Inspector General, Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing, OEI-02-17-00250, available at https://www.oig.hhs.gov/oei/reports/oei-02-17-00250.pdf
[3] Cite Part D rule
[4] HHS Office of Inspector General, Semiannual Report to Congress, November 2017 (pg. 6) available at https://oig.hhs.gov/reports-and-publications/archives/semiannual/2017/sar-fall-2017.pdf
[5] Ibid.
[6] NAVIPPRO Internet Survey Report. Prepared for KemPharm; March 2016**Source**

reducing prescription opioid abuse than focusing alone on a post-addiction treatment regimen as the result of abuse.[7]

While the FDA has encouraged the development and licensure of AD opioids—ten AD opioids have received a label of abuse deterrence by the FDA and 6 are currently available on the market—utilization remains very low.[8] As FDA Commissioner Scott Gottlieb, M.D., has noted, "[AD opioid] uptake has been slow among doctors who are treating patients in pain. The reason for their more limited use is likely multifold. We know there can be a learning curve that comes with new technologies. Some prescribers may not be aware of the existence of these drugs, or may be uncertain of when to prescribe the abuse-deterrent versions. But we also know a significant barrier to use can be price."[9]

To more effectively combat the prescription opioid abuse crisis, CMS has an opportunity to provide valuable assistance to Part D plans to ensure both improved education among providers, particularly those treating at-risk beneficiaries, as well as adequate access to AD opioids on plan formularies.

CMS should instruct Medicare plans on the need to educate providers on prescription opioid abuse prevention and mitigation efforts, including the use of AD opioids. In the 2017 plan year, many Part D plan sponsors did not include AD opioids on their allowable prescription drug formularies; and even in instances when the AD opioid was technically a covered service, many plans employed a variety of coverage restrictions, preauthorization, "fail-first" and other formulary tools to limit provider choice and deter greater patient access to AD opioids.

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[7]: Medical cost savings associated with an extended-release opioid with abuse-deterrent technology in the US. *US Journal of Medicinal Economics. March 2016.*

[8] AD opioids constituent less than 4 percent of the total opioid marketplace in Medicare Part D. need cite

[9] Statement from FDA Commissioner Scott Gottlieb, M.D., on steps to promote development of generic versions of opioids formulated to deter abuse. Nov. 21, 2017. Available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm586117.htm

While these drug management techniques are not unique, due to the gravity of the prescription opioid abuse crisis several states have enacted policies in commercial markets to:

- Cover AD opioids on formularies on a basis that is not less favorable than non-AD opioid products;
- Prohibit plans from requiring patients to "step through" a non-AD opioid before receiving an AD opioid;
- Require coverage of AD opioids at the same cost-sharing tier as non-AD opioids; and
- Require prior authorization for AD opioids only if prior authorization for non-AD opioids is also required.[1]

As Dr. Gottlieb has stated, "Transitioning from the current market, dominated by conventional opioids, to one in which most opioids have abuse-deterrent properties, holds significant promise for a meaningful public health benefit," we urge the CMS to review plan formularies to ensure adequate access to AD opioids and consider formulary management restrictions where appropriate.

In the Proposed Rule, CMS identified more than 300,000 beneficiaries potentially at risk for opioid abuse because of very high prescribing patterns – and has suggested that these individuals are responsible for potentially hundreds of millions of abuseable opioid tablets that could be diverted to improper use every year.[10] The CMS is one agency playing a critical part in our national opioid response. By adding its support for the appropriate substitution of AD opioids for those identified as "at-risk" Part D beneficiaries, it could potentially serve a very important role in deterring the illegal diversion of prescription opioids.

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[1] See: Massachusetts: Mass. Gen. Laws ch. 258, §9 (2015) available at https://malegislature.gov/Laws/SessionLaws/Acts/2014/Chapter258; Florida: Fla Stat. §422 (2016) available at https://www.flsenate.gov/Session/Bill/2016/0422/ByVersion; Maryland: Md. Ins Code § 15-849 (2015) available at http://law.justia.com/codes/maryland/2015/article-gin/title-15/subtitle-8/section-15-849; West Virginia: W. Va Code §4146 (2016) available at: http://www.legis.state.wv.us/Bill_Status/bills_text.cfm?billdoc=HB4146%20SUB%20ENR.htm&yr=2016&sesstype=RS&i=4146; Maine: 24-A MRSA §4320(2016) available at https://legislature.maine.gov/legis/bills/bills_127th/billtexts/HP063801.asp.

[10] 300,000 beneficiaries' x 60 opioid pills month x 12 months = 216,000,000.

Recommendation:

As AD opioids are designed, and appropriately prescribed, for patients with acute or chronic pain, the undersigned Members of the ADC urge the CMS to consider and encourage substitutable utilization of AD opioids over existing and more abusable versions of the same non-abuse deterrent moiety formulations in the context of the Part D Opioid Overutilization Policy and Overutilization Monitoring System.

The CMS has the authority to make the recommended policy change:

Prior to implementation of the Medicare Part D benefit, the CMS created the six protected classes, designed to ensure access to treatments for certain highly sensitive diseases. The CMS used its authority under the "anti-discrimination" clause in the statute to provide these protections. It was not until 2008 when Congress enacted the Medicare Improvements for Patients and Providers Act (MIPPA) that the six protected classes were established in statute and required Medicare Part D drug plans to include access to all or substantially all drugs in the six identified categories. In 2010, Congress made further modifications to the protected classes, including the authority to "identify, as appropriate, categories and classes of drugs for which the Secretary determines are of clinical concern."[11]

Similarly, CMS could use its general authority under the "anti-discrimination" clause in 1860D-(4), that it used to establish protections for certain drugs or the more explicit authority under the "classes of clinical concern" to ensure proper Medicare beneficiary access to AD opioids.

CMS also proposes at § 423.100 to designate **all** (emphasis added) opioids as "frequently abused drugs," excepting buprenorphine for medication-assisted treatment (MAT) and injectables. The AD Coalition urges the CMS to exclude AD opioids from this definition of "frequently abused drug" as there is no evidentiary data to support the thesis that AD opioids are frequently abused and existing observation data supports their exclusion from this broad standard.[12]

[11] Pub. L. 111-148, 124 Stat. 119 (March 23, 2010).

[12] "Effect of Abuse-Deterrent Formulations and IR Opioids on Abuse, Overdose and Death from Rx Opioids" presentation to NASACA, Richard C. Dart, MD, PhD, Executive Director Denver Health and Hospitals Authority (RADARS) Slides 12-16 (October 17, 2017).

President Trump has declared the opioid abuse crisis a nationwide public health emergency. The FDA's Opioid Action Plan incorporates AD opioids as a critical tool in the effort to reduce abuse, misuse and diversion of prescription opioids. The CMS can add to the effort to promote the deterrence of the deliberate misuse, abuse and deterrence of prescription opioids by ensuring appropriately broad and favorable Medicare beneficiary access to AD opioids by allowing complete and equitable formulary access to these innovative products.

Sincerely,

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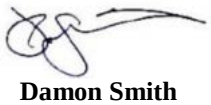

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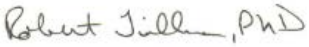

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