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Submitted Electronically via Regulations.gov

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1715-P
Mail Stop C4-26-05,
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1715-P: AdvaMed Comments on Proposed Open Payments Regulations, ICRs Regarding the Open Payments Program, and Proposed Amendments to Physician Self-Referral Law Advisory Opinion Regulations

Dear Administrator Verma:

On behalf of the members of the Advanced Medical Technology Association (“AdvaMed”), we submit this letter to provide comments on the following three parts of the Department of Health and Human Services, Centers for Medicare & Medicaid Services (“CMS”) proposed rule associated with the 2020 Physician Fee Schedule (“Proposed Rule”):¹

- (A) Proposed Changes to Open Payments Regulations;²
- (B) Information Collection Requirements regarding the Open Payments Program;³ and
- (C) Proposed Amendments to the Physician Self-Referral Law Advisory Opinion Regulations.⁴

¹ Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations, 84 Fed. Reg. 40482 (Aug. 14, 2019).

² *I.d.* at 40713 (Open Payments (Section III.F.))

³ *I.d.* at 40840 (Information Collection Requirements Regarding the Open Payments Program (Section IV.B.5.))

⁴ *I.d.* at 40726 (Aug. 14, 2019) (Advisory Opinions on the Application of the Physician Self-Referral Law (Section III.J.))

This letter sets out AdvaMed's comments on the Proposed Rule's sections III.F., IV.B.5., and III.J. only. Separately, AdvaMed submits comments regarding all other proposed revisions to payment policies under the CY2020 Physician Fee Schedule, Other Changes to Part B Payment Policies, and other provisions set out in the Proposed Rule (file code CMS-1715-P).

AdvaMed Background

AdvaMed is the world's largest trade association of medical device manufacturers who produce the medical technologies that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed represents over 400 manufacturers of medical devices, diagnostics, and health information systems. AdvaMed's member companies range from the largest to the smallest medical technology innovators and companies.

AdvaMed supports and has proactively embraced appropriate disclosure of relationships between medical technology companies and physicians. We and our member companies recognize that strong ethical standards are critical to ensuring appropriate collaboration between the medical device industry and health care professionals (HCPs) to produce the world's most advanced medical technologies. AdvaMed has updated its Code of Ethics on Interactions with Health Care Professionals in the United States ("AdvaMed Code").⁵ The updated code, effective January 1, 2020, continues to clarify and distinguish appropriate activity between health care professionals and representatives of AdvaMed member companies. The AdvaMed Code has been updated to bring examples current, to enhance user-friendliness, to address the evolving nature of HCP interactions, and to provide greater clarity in the following areas:

- Commercial & sponsorships, educational grants;
- Co-conducted education & marketing programs;
- Meals with HCPs;
- Communicating in the safe and effective use of medical technology
- Evaluation, demonstration, and consignment products; and
- Industry technical support in the clinical setting.

AdvaMed has taken aggressive steps to educate the industry and health care professionals about the Code, ethical interactions, and compliance.

AdvaMed seeks to continue its open dialogue with CMS regarding the realities and challenges of the Open Payments program and the importance of serving the legislative intent of providing patients with clear, meaningful information concerning industry relationships, without

⁵ Available at: <https://www.advamed.org/issues/code-ethics/code-ethics>

discouraging beneficial interactions critical to the development and safe and effective use of innovative medical technologies.

A. OPEN PAYMENTS PROPOSED CHANGES (Section III.F.1.C.)

(1) EXPANDING THE DEFINITION OF A COVERED RECIPIENT

- 1. AdvaMed recommends that CMS provide a validated list of covered recipients added by the SUPPORT ACT with the license numbers that will be accepted by the reporting system. If providing a validated list is not initially feasible, AdvaMed recommends that CMS specify the data source(s) that may be relied upon to determine whether a practitioner is a covered recipient and further clarify the license type(s) that the reporting system will accept.**

A top priority concern is with the matching or validation process for the four APRN roles that the SUPPORT ACT adds as covered recipients—Nurse Practitioners (NPs), Certified Nurse Specialists (CNSs), Certified Registered Nurse Anesthetists (CRNAs), and Certified Nurse-Midwives (CNMs). This is a concern because:

- a number of NPs, CNSs, CRNAs, and CNMs do not currently have a National Provider Identifier (NPI) number;
- the licensing framework for these APRNs roles vary by state; and
- the proposed definitions may deem some APRNs as covered recipients without an advanced practice license, based only on Registered Nurse (RN) licensure with some types of certification or education.

The CMS National Plan and Provider Enumeration System (NPPES) cannot be utilized as a source for identifying practitioner types because the types are self-reported. For example, one NP selected “207Q0000X - Family Medicine” for the primary taxonomy in the NPPES while listing only her RN license number.⁶ Further, no APRN role is listed following her name.

NPs, CNSs, CRNAs, and CNMs that do not have their own NPI number often provide the NPI number of the physician they are in a collaborative agreement with. This would also complicate the use of national provider identifiers in open payments reporting.

We have not been able to identify a source for APRN licensure across the country that is readily available on a public or commercial basis. APRN licensing data for an individual practitioner can vary by the source, resulting in many failed matches. Further, the licensing framework for APRNs varies and does not uniformly align with the definitions proposed for some APRNs. Given the

⁶ See NPI Registry example [https://npiregistry.cms.hhs.gov/registry/provider-view/\[REDACTED\] \[REDACTED\]](https://npiregistry.cms.hhs.gov/registry/provider-view/[REDACTED] [REDACTED]) compared to NURSYS QuickConfirm License Verification Search by NCSBN IDL [REDACTED] [REDACTED]

above, AdvaMed recommends that CMS prioritize the issuance of a validated list of the additional covered recipients added by the SUPPORT ACT that includes license and/or registration number(s) that the Open Payments reporting system will accept.

If CMS is not initially able to provide a validated list of covered recipients, CMS should disclose the data sources and logic that will be applied to determine whether a practitioner is a covered recipient. The logic will need to address how interstate variations in identifying these covered recipient types should be handled. The examples below illustrate the kinds of issues that arise when attempting to determine whether a practitioner is a covered recipient and which license/registration/certification number should be submitted in the reporting.

- Some states issue multiple license numbers to an individual APRN (e.g., Vermont assigns two different license numbers for APRNs, one for the RN license and another number for the APRN license). If a validated list of APRN covered recipients is not provided initially, guidance is needed on whether only one or both license numbers will be accepted.
- In some states, there is no separate APRN license, and a licensed RN obtains prescribing authority through certification. For example, in Wisconsin, RNs must obtain a certification as an Advanced Practice Nurse Prescriber (APNP) to have the authority to issue prescriptions.⁷ Nurse-Midwives in Wisconsin must have an additional Nurse-Midwife license,⁸ but NPs, CNSs, and CRNAs only need the APNP certification.⁹ Should the APNP Certification number be provided instead of a license number?
- Some states do not have individual licenses for all four of the specified APRN roles (NP, CNS, CRNA, CNM) in the Support Act and instead have a single APRN license that covers more than one APRN role. In Connecticut, there are only two license types (APRN and Midwife) for all APRN roles. Registered nurses can obtain APRN licensure if they hold and maintain certification as an NP, CNS, or Nurse Anesthetist from one of seven national organizations.¹⁰ Registered nurses can obtain a Midwife License if they hold current certification by the American Midwifery Certification Board.¹¹ In Idaho there is one

⁷ Laura A. Stokowski, RN, MS, *APRN Prescribing Law: A State-by-State Summary*, MEDSCAPE, Jan. 4, 2018, <https://www.medscape.com/viewarticle/440315>

⁸ <https://dsps.wi.gov/Pages/Professions/NurseMidwife/Default.aspx>

⁹ <https://dsps.wi.gov/Pages/Professions/APNP/Default.aspx>

¹⁰ APRN Licensure Requirements, Connecticut State Department of Public Health <https://portal.ct.gov/DPH/Practitioner-Licensing--Investigations/APRN/APRN-Licensure-Requirements>

¹¹ Midwife Licensure Requirements, Connecticut State Department of Public Health <https://portal.ct.gov/DPH/Practitioner-Licensing--Investigations/Midwife/Midwife-Licensure-Requirements>

Advanced Practice Professional Nurse (APPN) license that covers NP, CNS, CRNA, and CNMs.¹²

- In Michigan, only the Registered Nurse license type is listed, and the APRN role (e.g., NP) is identified under “Specialty.”
- Massachusetts lists two license types for APRNs (the RN and the APRN license) but utilizes the same license number in both listings.

In addition, CMS should publish a list of all credentials, license types, specialties, and professional suffix codes per state that would be considered reportable if actively licensed in that state under that credential or professional suffix and update the list annually until a validated list of covered recipients is released. For example:

State	Reportable Credentials, Specialties, or Professional Suffixes	Displayed as per State Licensure Site
Alabama	<ul style="list-style-type: none"> • Adult Nurse Practitioner [ANP] • Advanced Practice Nurse [APN] • Advanced Practice Registered Nurse [APRN] • Advanced Nurse Practitioner [ANP] • Advanced Practice Nurse Prescriber [APNP] • Certified Nurse Practitioner [CNP, NP-C] • Clinical Nurse Specialist [CNS] • Certified Registered Nurse Anesthetist [CRNA] • Certified Nurse Registered Practitioner [CRNP] • Certified Nurse-Midwife [CNM] • Geriatric Nurse Practitioner [GNP] • Family Nurse Practitioner [FNP] • Nurse Practitioner [NP] <p>(This list is for demonstration purposes only and is not a confirmed listing for Alabama)</p>	License Type
Alaska	Etc.	
Arizona		

¹² Rules of the Idaho State Board of Nursing <https://adminrules.idaho.gov/rules/2000/23/0101.pdf>

While this credential list by state would not help with specific license matching issues (or for those instances where a license is not issued for a CNS or CNM, etc.) such a list would help Applicable Manufacturers identify and target reportable credentials by state.

- 2. AdvaMed recommends that CMS revise the proposed definitions of Certified Nurse Midwife and Clinical Nurse Specialist to also require an advanced practice license or another registration that demonstrates prescribing authority (e.g., Controlled Substance Registration or DEA Registration Number). If such registration information is not publicly available (e.g., DEA Registration Number), a list of CNMs and CNSs identified by CMS's access to that registration information should be made available to manufacturers along with the license/certification type and number that will be accepted by the reporting system.**

The Proposed Rule defines Certified Nurse Midwife by reference to the definition in Section 1861(gg)(2) of the Social Security Act, which states:

The term “certified nurse midwife” means a registered nurse who has successfully completed a program of study and clinical experience meeting guidelines prescribed by the Secretary, or has been certified by an organization recognized by the Secretary.

This definition of CNM does not appear to require an advanced practice license, merely certification by a recognized organization. For example, in Connecticut, a registered nurse can hold current certification by the American Midwifery Certification Board, but not possess a current Midwife license if he/she did not also complete thirty hours of education in pharmacology for nurse-midwifery.¹³ If such an individual were deemed to be a covered recipient, it would not be based on an advanced practice license, and one would need to cross-check every RN against the those who hold a current certification by the American Midwifery Certification Board (AMCB). Compounding this, there does not appear to be a publicly accessible list of current AMCB certified practitioners and the AMCB website only provides for verification on an individual practitioner basis.¹⁴

The Proposed Rule defines Clinical Nurse Specialist by reference to the definition in Section 1861(aa)(5)(B) of the Social Security Act, which states:

¹³ Midwife Licensure Requirements, Connecticut State Department of Public Health
<https://portal.ct.gov/DPH/Practitioner-Licensing--Investigations/Midwife/Midwife-Licensure-Requirements>

¹⁴ See <https://www.amcbmidwife.org>

The term “clinical nurse specialist” means, for purposes of this title, an individual who— (i) is a registered nurse and is licensed to practice nursing in the State in which the clinical nurse specialist services are performed; and (ii) holds a master’s degree in a defined clinical area of nursing from an accredited educational institution.

This definition of CNS only appears to differentiate RNs from CNSs by whether a master’s degree in a defined clinical area from an accredited educational institution was previously obtained. If such an individual were deemed a covered recipient, it would not be based on an advanced practice license or prescribing authority. We are not aware of any practical means of crosschecking RNs against master’s degree holders from accredited institutions in a defined clinical area of nursing.

For practicality and consistency with other covered recipients, the definition of Certified Nurse Midwife and Clinical Nurse Specialist should require an advance practice license or another registration that demonstrates prescribing authority that is publicly accessible.

(2) NATURE OF PAYMENT CATEGORIES

AdvaMed greatly appreciates CMS’s integration of three new nature of payment categories recommended in our September 1, 2016 comment letter on the Open Payments provisions in the 2017 Physician Fee Schedule proposed rule. The new categories for Debt Forgiveness, Long-Term Medical Supply or Device Loan, and Acquisitions will improve the accuracy of the data disclosed and facilitate clearer, more meaningful reporting.

AdvaMed recommends integrating clarifying language in the preamble that the scope of the Acquisitions nature of payment category includes stock, asset, and intellectually property purchases.

AdvaMed also endorses the proposed consolidation of § 403.904(e)(2)(xiv) and (xv) into one nature of payment category for medical education programs.

(3) STANDARDIZING DATA ON REPORTED COVERED DRUGS, DEVICES, BIOLOGICALS, OR MEDICAL SUPPLIES

- 1. The proposal to revise § 403.904(c)(8) to require submitting the Device Identifiers for each marketed name device associated with a transfer of value (“Device Identifier Proposal”) will often not provide meaningful information to public users of Open Payments data for two reasons—(1) many common single transfers of value are associated with a multitude of Device Identifiers**

and (2) product discussions occur around product lines and systems, not about the products identified by a set of Device Identifiers at that point in time—both of which can create an inaccurate or misleading picture.

The Device Identifier is the mandatory, fixed portion of a Unique Device Identifier that identifies the specific version or model of a device and the labeler of that device.¹⁵ Many device manufacturers have tens of thousands of Device Identifiers, and several companies have well over one-hundred thousand Device Identifiers. If a transfer of value is related to a marketed name device, it frequently occurs in the context of product discussions or product training.¹⁶ Often a transfer of value in these contexts relates to product line or system, comprised of numerous individual marketed name devices that are components and options within that product line or system. Many individual products are associated with multiple Device Identifiers because a different Device Identifier is required for each variation and version. For example, one company has 31,488 different Device Identifiers for reusable basic tracheostomy tubes with tube cuffs (FDA produce code JOH).¹⁷ Another company has 9,189 different Device Identifiers for spinal fixation pedicle screws for degenerative disc disease.¹⁸ There is a different Device Identifier for each variation in diameter, length, composition, coating, screw head and body connection (monoaxial, polyaxial, and uniplanar), thread depth, thread pitch, and version/model. Further, the pedicle screw is only one part of a spinal fixation system. Other components of a spinal fixation system include rods, rod connectors, plates, laminar hooks, and other types of connectors, where each component has different variations, and some variations have multiple versions, each of which requires a distinct Device Identifier. While some marketed name products may correspond to fewer than 20

¹⁵ 21 C.F.R. 801.3

¹⁶ E.g., See Open Payments Record ID [REDACTED] general payment record identifying Food and Beverage provided as an In-kind item to [REDACTED] [REDACTED] [REDACTED] with a total value of \$122.50 related to product discussions on the [REDACTED] [REDACTED] System, [REDACTED], and the [REDACTED] [REDACTED] System. [https://openpaymentsdata.cms.gov/physician/\[REDACTED\]](https://openpaymentsdata.cms.gov/physician/[REDACTED]) [REDACTED]

¹⁷ See AccessGUDID website [https://accessgudid.nlm.nih.gov/devices/search?filters=\[REDACTED\]](https://accessgudid.nlm.nih.gov/devices/search?filters=[REDACTED]) [REDACTED] [REDACTED] [REDACTED] [REDACTED] (last visited Sept. 27, 2019) [REDACTED]

¹⁸ See AccessGUDID website [https://accessgudid.nlm.nih.gov/devices/search?filters=\[REDACTED\]](https://accessgudid.nlm.nih.gov/devices/search?filters=[REDACTED]) [REDACTED] [REDACTED] [REDACTED] [REDACTED] (last visited Sept. 27, 2019) [REDACTED]

Device Identifiers, transfers of value related to many marketed name products and product systems will require reporting hundreds to thousands of Device Identifiers per product or system.

Further, some distributors engage covered recipients in product discussions that relate to product systems/lines from several different manufacturers. For example, a distributor's discussion with a covered recipient about in vitro diagnostic systems would relate to several manufacturers' systems, each system associated with numerous Device Identifiers for the machine and its reagents, calibrators, controls, and washes. On top of that, each size variation of a reagent, calibrator, control, or wash requires a different Device Identifier. The inclusion of thousands of Device Identifiers within a single general payment record (e.g., in-kind food and beverage that relates to a product discussion) distorts or confuses the picture for the following reasons: (1) each component, variation, and version was not actually discussed; (2) in actuality the marketed name product system was discussed with coverage of some individual components; and (3) the high volume of Device Identifiers for a single transfer of value can dilute the weight associated with a transfer of value (viewing the payment on a per Device-Identifier basis).

In many examples, versioning can occur at a very granular level with a multitude of versions available on the market at the same time for a single product. A separate version or model is permitted for all devices that have specifications, performance, size, and composition, within limits set by the labeler.¹⁹ This can result in a temporal discrepancy between the Device Identifiers associated with a marketed name device at the time of the transfer of value and the Devices Identifiers at a future point in time when a patient will be treated by a covered recipient. The Device Identifiers reported with a past transfer of value related to a marketed name device will not include Device Identifiers from newer versions of the same marketed name device that became available after the date of the transfer of value. For many instances, a discussion about a product line or system would also relate to specific newer versions. For those circumstances, a more meaningful listing of relevant Device Identifiers would be obtained when patients search the Global Unique Device Identification Database (GUDID)²⁰ for the reported marketed names on the date a covered recipient prescribes or recommends a procedure utilizing that marketed name device.

2. Substantial effort, money, and time will be needed to develop and implement the systems required to operationalize the Device Identifier Proposal because there is no current product hierarchy among Device Identifiers that corresponds to marketed name products and systems.

¹⁹ 78 Fed. Reg. 58786, 58818

²⁰ The Global Unique Device Identification Database (GUDID) is a searchable Device Identifier database that includes the device identification information submitted to the FDA. <https://accessgudid.nlm.nih.gov/about-gudid#what-is-gudid>

All of the members of AdvaMed's Sunshine Implementation Working Group reported that a marketed name product and marketed name system hierarchy does not exist within the Device Identifiers utilized by their company. Although it is possible to generate a list of related device identifiers on the back end after an expense report associated with a transfer of value is submitted, individual determinations would need to be made about the inclusion or exclusion of each Device Identifier version model associated with a Marketed Name/Brand Name until a hierarchy system is created.

3. AdvaMed requests that CMS dialogue with industry before finalizing the Device Identifier Proposal to explore alternatives and develop a more accurate understanding of the time, effort, and cost to develop and implement the systems needed to execute this proposal.

AdvaMed respectfully requests that CMS reconsider the proposal to revise § 403.904(c)(8) to require submitting the Device Identifiers for each marketed name device associated with a transfer of value in light of the potential for distorting transfers of value and flooding such transfers of value with so many Device Identifiers that the data becomes functionally meaningless to public users of the open payments data. AdvaMed would be grateful for the opportunity to dialogue with CMS on potential alternatives that could generate more specific information about devices associated with transactions and enhance the usefulness of Open Payments data to the public.

If the Device Identifier Proposal is finalized without exploring alternatives, AdvaMed requests that CMS grant Applicable Manufacturers latitude and discretion to select a representative Device Identifier (among applicable Device Identifiers) to associate with a Marketed Product Name.

B. INFORMATION COLLECTION REQUIREMENTS REGARDING THE OPEN PAYMENTS PROGRAM (SECTION IV.B.5.)²¹

The Paperwork Reduction Act cost and burden estimates dramatically undervalues the anticipated true costs of the proposed changes to the Open Payments Program on the medical device industry. AdvaMed conducted an informal survey of its members, demonstrating that CMS should revisit its burden estimates and conduct a formal, statistically significant study of applicable manufacturers and group purchasing organizations to measure more accurately how much companies will actually need to spend to comply.

In particular, the burden for changes to standardize data on reported covered devices and medical supplies (the Device Identifier Proposal) is alarmingly undervalued. The estimate of hours of support staff and compliance officer time appears to assume a total number of Device Identifiers that is orders of magnitude lower than what currently exists, and further implies that some product

²¹ 84 Fed. Reg. 40482, 40840 (Aug. 14, 2019).

and system hierarchy already exists, which is not the case. To develop the new systems needed, substantial hours will also be required of regulatory and UDI experts, IT integration consultants, and database professionals.

**C. PROPOSED AMENDMENTS TO THE PHYSICIAN SELF-REFERRAL LAW
ADVISORY OPINION REGULATIONS (Section III.J.2)**²²

Although most of AdvaMed's members are not directly impacted by the Physician Self-Referral Law, some of our members provide Designated Health Services, as defined at 42 U.S.C. 1395nn(h)(6) and 42 C.F.R. 411.351.

AdvaMed is generally supportive of CMS's proposed amendments to the physician self-referral law advisory opinion regulations. AdvaMed especially supports the proposal at § 411.387(c) to recognize that individuals and entities other than the requestor may reasonably rely on an advisory opinion as guidance that illustrates the application of the self-referral law and regulations to specific facts and circumstances. Similarly, AdvaMed endorses the proposal at § 411.387(b) specifying that the Secretary will not pursue sanctions under section 1877(g) of the Act against any individuals or entities that are parties to an arrangement that is indistinguishable in all material aspects from an arrangement that was the subject of a favorable advisory opinion.

AdvaMed recommends that CMS's right to rescind or revise an advisory opinion (under §411.382) be limited to two instances—(1) when there is a material statutory or regulatory change that impacts the conclusions reached, and (2) when a party asks the agency to reconsider based on new information. AdvaMed further recommends that CMS's right to rescind or revise an advisory opinion only follow a reasonable period of public notice of no less than 30 days, given the proposed expansion of protection to non-requestors.

* * *

Thank you in advance for your consideration of the above recommendations and requests. We would be pleased to discuss any aspect of this letter in greater detail at your convenience and provide additional information or examples that may be of interest. Please do not hesitate to contact me at (202) 783-8700 or cwhite@advamed.org with any questions.

Sincerely,

/s/

Christopher L. White
Chief Operating Officer and General Counsel
Advanced Medical Technology Association (AdvaMed)

²² *I.d.* at 40727 (Aug. 14, 2019) (Proposed Revisions to the CMS Advisory Opinion Process and Regulations (Section III.J.2.))