MDMA
MEDICAL DEVICE MANUFACTURERS ASSOCIATION

1333 H Street, NW
Suite 400W
Washington, DC 20005
Phone (202) 354-7171
Fax (202) 354-7176

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**** Via Electronic Submission ****

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS–1751–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

RE: Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements [CMS–1751–P]

Dear Administrator Brooks-LaSure,

The Medical Device Manufacturers Association (MDMA) appreciates the opportunity to provide the following comments to the proposed revisions to the Medicare Physician Fee Schedule (PFS) for calendar year (CY) 2022 (the "Proposed Rule").[1]

For nearly 30 years, MDMA has represented the medical device industry in Washington, DC, supporting policies that promote medical innovation and patient access to lifesaving and life-changing medical technologies. MDMA's membership is broad and diverse, ranging from small start-ups to multi-national medical device companies. It is a long and risky venture to develop novel medical innovations, and those that succeed have changed the face of medicine and redefined what is possible in the diagnosis and treatment of deadly diseases and prevalent conditions like cancer, heart disease, diabetes, and stroke.

We support the efforts of the Centers for Medicare and Medicaid Services (CMS) to improve the accuracy of payment rates and ensure that providers are incentivized to provide high quality care

[1] 86 Fed. Reg. 39,104 (July 23, 2021).

in an efficient manner. Medicare's payment rates must accurately reflect the costs of providing appropriate care in order to ensure that beneficiaries have access to the best care available today and that providers can invest in the technologies that will allow care to continue to improve.

In order to ensure that the PFS continues to provide Medicare beneficiaries access to appropriate, innovative care, MDMA asks CMS to take the actions set forth below.

I. CMS should defer the proposed update to clinical labor data used to calculate direct practice expense until the agency and stakeholders have a fuller opportunity to understand the negative impact on office-based specialists and on beneficiary access to device-intensive procedures, and to consider and comment on alternative approaches to mitigate that impact.

If the Proposed Rule is implemented as written, the most significant impact on providers, practice patterns and Medicare beneficiaries is likely to result not from a change in policy or statutory interpretation, but from the agency's proposal to update the clinical labor data used to calculate direct practice expense (PE).[2] That data has not been updated since 2002, so the ultimate goal is one we support. However, while achieving that objective appears simple and straightforward, there are important policy considerations and choices involved. Moreover, as MDMA and other stakeholders have modeled the potential impact, it has become increasingly clear that updating the clinical labor data in the manner that CMS has proposed will cause substantial reductions in nonfacility payment for many procedures—reductions that could eliminate the physician office as a viable setting of care and reduce treatment options for beneficiaries who may have difficulty accessing a hospital outpatient department (HOPD) or ambulatory surgery center (ASC). **We strongly believe that, given the magnitude of the changes in payment and the potential for such a significant adverse impact on providers and beneficiaries, CMS should take more time to evaluate the policy choices involved, potential alternative approaches and relative impacts, and to gather input from stakeholders on the best path forward.**

According to an analysis done by Medical Technology Partners, an MDMA member company, over 600 procedures are facing a proposed reduction in nonfacility payment of more than 10% in CY 2022, with some reductions approaching 25%. Another nearly 700 codes will be reduced between 5-10%. These reductions are the result of CMS administrative policies relating to PFS budget neutrality, and specifically the agency's policy of maintaining budget neutrality within the direct PE pool. Condensing nearly 20 years of labor inflation into a single annual payment update would cause the total direct PE pool to go up 32%, and the "direct adjustment factor"—used by CMS to enforce its budget neutrality policy—to decrease from 0.5916 to 0.4468. In other words, Medicare will now reimburse 44 cents on the dollar in CY 2022, instead of 59 cents on the dollar in CY 2021, for supply and equipment costs included in direct PE.

As suggested above, the extent of the reductions was not readily apparent when the Proposed Rule was first issued by CMS. One reason for this is that the impact tables included with the Proposed Rule only illustrate the aggregate impacts on different medical specialties and do so without regard to site-of-service. They do not illustrate, and in fact can mask, more significant changes in payment

[2] *Id.* at 39,118.

for individual procedures in the nonfacility setting that are just as important, if not more so, as aggregate impact when it comes to beneficiary access.

The risk that the proposed payment reductions would eliminate the physician office as a potential site of service for certain procedures should not be viewed as overly speculative. Three examples clearly demonstrate that risk:

- Prostatic urethral lift (PUL) is a procedure to treat benign prostatic hyperplasia (BPH). It is described by CPT 52441, which includes a single implant, and the add-on code CPT 52422 for each additional implant. PUL is currently performed by physicians in the office, as well as in the HOPD or ASC setting, and clinical evidence supports the safety and efficacy of the procedure when performed in all settings, including the physician office. For CY 2022, CMS is proposing to reimburse physicians performing PUL in the office setting $3,543 for a typical 4-implant procedure, as opposed to $4,493 in CY 2021—a reduction of $950, or more than 21%. The total cost of just the four implants is $3,500. Thus, only $43 would be left to cover the cost of other supplies necessary for completing the service ($220.05), 150.5 minutes RN labor, equipment costs, malpractice costs, and indirect costs, plus the physician's 7.03 RVUs of work.

- Many patients suffering from prostate cancer choose to receive rectal spacers prior to beginning radiation therapy, in a procedure described by CPT 55874, *Transperineal placement of biodegradable material, peri-prostate, single or multiple injection(s), including image guidance, when performed*. The biodegradable material increases the space between the prostate and rectum, reducing the often-debilitating side effects of irradiating healthy tissue, including potentially chronic complications for which treatment and management can result in additional cost to Medicare, and potentially enabling higher doses of radiation in fewer rounds of treatment. Prior to this proposed ruling, it is estimated that up to 14,000 Medicare patients would receive this procedure in 2022, with approximately 50 percent taking place under local anesthesia within the physician office setting. The proposed non-facility payment of $2,565.54 for CPT 55874 for CY 2022—a reduction of $580.40, or 18%, from CY 2021—is below the cost of the material alone. That underpayment is likely to shift a significant amount of procedure volume to the HOPD setting, a higher-cost setting. It also could create barriers to access for beneficiaries, especially during the current pandemic.

- CMS is proposing to reduce the payment of Disposable Negative Pressure Wound Therapy (dNPWT), CPT codes 97607 and 97608, by 22%. We understand that physicians in 21 states would receive non-facility reimbursement below the acquisition cost of the therapy under the Proposed Rule. The option to use dNPWT provides numerous benefits to patients and improves their quality of life. dNPWT is portable, light weight and allows for patients to be mobile rather than house bound while using this therapy. We have significant concerns that this drastic reduction will make it nearly impossible for physicians to continue to use this therapy in providing care to their patients. If CMS moves forward with this decrease, reduced access to this therapy could result in some patients forgoing treatment for wounds, resulting in poorer outcomes, while other patients will be forced to

seek care in the hospital outpatient setting. Both would result in higher costs to the Medicare program.

It is difficult to believe that office-based physicians will continue offering a service for which the Medicare payment fails to cover even the cost of supplies—let alone physician work, malpractice expenses and other costs. CMS should avoid knowingly creating incentives that lead to an unnecessary shift of office procedures to more costly and less accessible facility settings.[3] And these three examples are by no means the only high-value office procedures that would be negatively affected by implementation of the Proposed Rule. It is also important to note that many communities do not have sufficient available resources in hospital settings to provide patient access to the services that will be impacted by this proposal. This shortage of outpatient facilities could be even more pronounced in the context of the COVID-19 epidemic.

As stated previously, we agree with the need to update the clinical labor inputs for direct PE. That said, more detail is needed in order for stakeholders to provide meaningful analysis and comment. **We do not believe that a phase-in alone will fully address the impact these severe payment cuts will have on office-based specialists and the beneficiaries who rely upon them for care. For device-intensive PFS services, CMS's proposed phase-in would only delay eventual unviability under the PFS rather than preventing it. It also would ignore the need for a fuller consideration of the policy options associated with updating the clinical labor data.**

The policy options that would benefit from further consideration include the various budget neutrality policies, including those applied within the PE pool and others that CMS uses to preserve the ratio between the PE pool and other components that make up the Relative Value units (RVUs) for each procedure. Other examples relate to the data that would be used to update the clinical labor inputs. The Proposed Rule identifies the general sources of wage data from the Bureau of Labor Statistics (BLS) used for the proposed update, but given the limited details about specific data points or adjustments, some important methodological choices—such as whether CMS used the mean or the median for the available measures of average wages, used wages for individuals employed by physician offices or a blend of wages across different types of employers, or used the same benefit multiplier applied to wage data in the 2002 update—are not apparent. MDMA believes that full transparency is needed in relation to the source data that will be used as part of this exercise, and that CMS should ensure that its cost inputs reflect costs in the physician office setting of care, rather than hospital-based settings.

Finally, MDMA believes that two factors support a conclusion that additional time and consideration would lead to a better methodology for updating the clinical labor PE data. First, the BLS has revised the estimation methodology for the Occupational Employment Statistics used in the clinical labor update and data using the new methodology will be available in Spring 2022. BLS believes the new methodology "substantially improved the accuracy and reliability of the

[3] CMS has recognized and addressed similar risks in other payment systems. The most notable example is under the regulations governing Medicare reimbursement to HOPDs and ASCs, where the agency has recognized that device costs do not differ between settings. CMS has created the device-intensive designation to avoid a reduction in the amount associated with nonvariable device costs that an ASC is paid relative to an HOPD due to the application of the ASC conversion factor.

estimates."[24] Second, CMS is in the midst of a comprehensive evaluation of options to improve PE data and methods, for which it has engaged the RAND Corporation. It would make sense to incorporate updates to the clinical labor data into the proposals that result from that evaluation to avoid multiple disruptive payment swings within a short period of time.

In summary, **we urge CMS to consider the serious concerns voiced by MDMA and other stakeholders about the methodology and impact of the clinical labor update proposal, and defer the update until the agency and stakeholders have fully explored alternative methodologies and implementation proposals that will not adversely and permanently affect patient access to numerous device-intensive office-based procedures.**

II. General Statement in Response to the Request for Information (RFI) Relating to Innovative Technologies Such as Artificial Intelligence (AI) and Software Algorithms

MDMA appreciates the careful and deliberative approach of CMS in seeking to better understand the growing use of AI and software algorithms in health care delivery, including direct application in the provision of care to beneficiaries, and in evaluating how these innovative technologies should be incorporated into Medicare payment systems. That includes the detailed RFI included in the Proposed Rule related to resource costs for physicians and other professionals paid under the PFS for adoption and utilization of innovative technologies such as AI.[5]

MDMA is a member of the AI Coalition, and we support the comments submitted by the AI Coalition in response to the RFI and other provisions of the Proposed Rule. In particular, we would like to reinforce the following points:

- There is immense potential for AI systems and AI-enabled and machine learning-enabled systems and medical devices—authorized by the Food and Drug Administration (FDA) and rigorously validated—to improve both individual care and the health care system in general. AI is being deployed in health care settings to better understand historic patient data, offer data-driven insights that may influence the patient plan of care, physician decision-making, and ultimately affect patient health outcomes, in addition to aiding in research for life-saving therapies. Other expected benefits from AI deployment include increasing access for Medicare beneficiaries in communities that lack certain health care services due to a lack of infrastructure or physicians, including the full range of medical specialists, as well as improvements in the quality of care.

- **As AI and machine learning-enabled systems are integrated into clinician workflow, there is unlikely to be a one-size-fits all answer to the overall impact on physician work.** AI services—like other medical services—are varied and diverse. In general, AI includes patient care tools for clinicians to deploy as they think most impactful to enhance good patient care. It also includes tools that allow the physician to access a deeper level of patient and other data, research, and information that can support treatment planning and

[4] *See* Bureau of Labor Statistics Monthly Labor Review, "Model-Based Estimates for the Occupational Employment Statistics Program" (August 2019), *available at* https://www.bls.gov/opub/mlr/2019/article/model-based-estimates-for-the-occupational-employment-statistics-program.htm.

[5] 86 Fed. Reg. at 39,125-39,126.

decision-making. While use of AI systems by physicians (or other qualified healthcare practitioners) could shorten the overall time to diagnosis or treatment in some cases, they could also give rise to additional services that increase overall physician work time and/or intensity with the enhanced access to more information.

- Healthcare providers recognize the value of healthcare AI tools and have made significant investments to integrate these innovative technologies into patient care. As with the services themselves, there are a wide range of arrangements depending on the type of AI and its historic use, though generally we do not see a one-time investment cost for these services. **MDMA believes that not all health care AI and machine learning systems should be classified as indirect PE, and that many (if not most) health care AI systems are more appropriately paid as direct PE.** We appreciate that CMS has responded positively to comments submitted by the AI Coalition in June that urged the agency not to delay access to AI services while potential modifications to indirect PE are being considered and noted concerns with contractor pricing, heeding that request and nationally pricing several AI services in the proposed PFS via crosswalk.

- **The potential for AI systems and software algorithms to perpetuate bias or discrimination in health care delivery, and the impact that may have on health equity efforts, is a legitimate concern and one that MDMA and the AI Coalition seek to collaboratively address with CMS and FDA**. CMS should consult with FDA as that agency integrates bias mitigation and a life cycle approach into oversight of the safety and efficacy of health care AI systems, as discussed at the FDA's Patient Engagement Advisory Meeting in October of 2020.[6]

We strongly support CMS's continuing efforts to ensure Medicare beneficiary access to AI services as the agency continues to evaluate issues relating to the PFS and other Medicare payment systems.

III. CMS should reconsider the proposed values for destruction of intraosseous basivertebral nerve (CPT Code 646X0 and 646X1).

CMS is proposing to establish relative values for two new Category I codes, CPT codes 646X0 and 646X1, used to report thermal destruction of intraosseous basivertebral nerve.[7] The agency is proposing values that are significantly lower than the values proposed by the RVS Update Committee (RUC). MDMA strongly urges CMS to reconsider the values that they have proposed for these codes. Finalizing the proposed RVUs will negatively impact upon patient access to care and the adoption of this technology, which fills a gap in the treatment algorithm of a subset of patients with chronic axial low back pain.

CMS is basing its proposed values on a crosswalk to CPT Code 63650, pointing to similarity between the two procedures in terms of intraservice time and total time. However, this

[6] U.S. Food & Drug Administration, "Patient Engagement Advisory Committee Meeting Announcement,"(October 22, 2020). Agenda and webcast available at https://www.fda.gov/advisory-committees/advisory-committee-calendar/october-22-2020-patient-engagement-advisory-committee-meeting-announcement-10222020-10222020.
[7] 86 Fed. Reg. at 39,164.

methodology ignores the results of the survey which utilized two spinal procedure codes (CPT codes 22514 and 22513), which are also 10-day global procedures and similar in technique. Even with the similarity in technique, survey responses indicated that destruction of intraosseous basivertebral nerve actually has greater intensity and complexity than CPT codes 22514 and 22513; yet the proposed valuation assigns lower intensity to the new codes.[8]. Additionally, these codes have total time that is significantly less.

Based upon the above, we urge CMS to reconsider the proposed values. We agree with CMS that the additional level code 646X1 should have a work RVU of approximately 50 percent of that assigned to CPT code 646X0.

IV. CMS should utilize carrier pricing for cataract removal with drainage device insertion.

For new Category I CPT codes 669X1 and 669X2, CMS also has proposed significant reductions to the work RVUs recommended by the RUC.[9] The proposed payment rates for these new codes, which represent a combination of a cataract procedure and a procedure for the insertion of an intraocular anterior segment aqueous drainage device, would result in a significant decrease in physician payments for this combined service compared to the current payments physicians receive when furnishing these services on the same day. We are concerned that these reductions will undermine beneficiary access to this treatment for patients with glaucoma and lessen the practical treatment options for physicians.

To preserve beneficiary access, CMS should defer the establishment of national rates and direct the MACs to determine physician payments for the new codes. The MACs already set rates for the insertion of the intraocular segment aqueous drainage device and will have to do so for a new code that is for this procedure without the cataracts procedure (CPT code 0X12T). This approach is similar to what CMS has used with another pair of codes that describe a combination of a cataract procedure and another procedure, as CMS notes in the Proposed Rule, explaining that it continues to believe that CPT codes 66987 and 66988 should continue to be contractor priced.[10] Should CMS wish to proceed with establishing national payment rates for new CPT codes 669X1 and 669X2, at the very least, it should utilize the RUC recommendations to establish the rates for these codes.

V. CMS should establish a national rate for external extended electrocardiographic monitoring to ensure Medicare beneficiaries have continued access to this important diagnostic procedure and technology.

CMS has requested additional public comment on the potential establishment of a national payment rate for external extended ECG monitoring, also known as long-term ECG (LT-ECG) monitoring, described by CPT codes 93241-93248.[11] As summarized in the Proposed Rule, CMS proposed national rates for the codes during the CY 2021 PFS rulemaking cycle based upon RUC recommendations; however, the agency ultimately finalized contractor pricing for four of the codes

[8] CPT codes 22514 and 22513 have intensity of work per unit of time (IWPUT) values of 0.053 and 0.056, respectively, while the Proposed Rule assigns an IWPUT of 0.040 to CPT codes 646X0 and 646X1.
[9] *Id.* at 39,164-39,165.
[10] *Id.*
[11] *Id.* at 39,178-39,179.

(CPT codes 93241, 93243, 93245, and 93247) that include a specific supply item, the ‘‘extended external ECG patch, medical magnetic tape recorder’’ (SD339), to allow additional time to consider appropriate pricing for the item.

LT-ECG monitoring has improved the ability of physicians to diagnose cardiac arrhythmias. Early detection of heart rhythm disorders, such as atrial fibrillation (AF) and other clinically relevant arrhythmias, allows for medical intervention and helps avoid more serious downstream medical events, including stroke. Unfortunately, as recognized in the Proposed Rule, drastic and inappropriate reductions in contractor pricing for the four relevant CPT codes since the CY 2021 Final Rule—resulting in contractor-based payments that no longer cover the acquisition cost for the SD339 supply item—are disrupting access for Medicare beneficiaries to this important diagnostic technology.

MDMA urges CMS to establish national payment rates for LT-ECG monitoring that enable Medicare beneficiaries to access these technologies at fair and stable rates representing relative resources typically used to furnish these services. Stakeholders' cost data representing typical resources used to furnish these services has been provided to CMS and can be used to value this service, or in the alternative, CMS should consider appropriate proposed crosswalks to a similar supply item pending more specific data CY 2023. Appropriate pricing would include crosswalks that represent a typical case and the marketplaces' independent diagnostic facility (IDTF) business models.

We believe CMS has sufficient data to establish an appropriate and fair cost for the item that also represents a typical case for these CPT codes and IDTF marketplace business models. We respectfully remind CMS that the RUC recommendations were already reviewed and generally accepted by CMS as part of the CY 2021 rulemaking cycle, and we believe they remain valid. In light of concerns about continued beneficiary access to LT-ECG under the contractor-priced rates, CMS should use the full extent of its authority to establish national rates rather than pursue an additional year of contractor-based payment.

VI. CMS should value evaluation and management (E/M) visits that are reimbursed as part of global surgery codes the same as identical E/M services reimbursed as standalone visits.

CMS is continuing to refine and update coding and payment policies for office/outpatient E/M visits, proposing changes to policies regarding split (or shared) visits, critical care services, and teaching physician visits for CY 2022.[12] However, the agency states that it is "continuing to assess values for global surgery procedures" and "this work is still ongoing."[13] As a result, CMS is proposing to continue *not* applying the E/M payment adjustments implemented on January 1, 2021 to the E/M portion of global codes, undervaluing those E/M services relative to the very same services paid on a standalone basis.

[12] *Id.* at 39,203-39,212.
[13] *Id.* at 39,211.

MDMA believes that the agency's current policy disrupts the relativity mandated by the Medicare statute,[14] and also violates statutory prohibitions on paying physicians differently for the same work.[15] We urge CMS to adjust the E/M component of all 10-day and 90-day global codes to reflect updated office/outpatient E/M code values.

VII. CMS should finalize its proposed modifications to 42 CFR § 410.33 to exempt those IDTFs that do not require direct or in-person beneficiary interaction, treatment, or testing from certain Medicare enrollment requirements and other regulations.

MDMA supports CMS' proposal to modify its regulations concerning IDTFs to provide greater flexibility for diagnostic testing providers who do not have in-person beneficiary interaction.[16] As CMS notes in the Proposed Rule, the current regulations concerning Medicare enrollment for IDTFs were designed for traditional IDTF suppliers that engage in direct or in-person beneficiary interaction, treatment, and/or testing. Increasingly, though, certain health care entities have developed or utilize diagnostic tests that do not require such in-person interaction, including tests which use off-site computer modeling or analytics. Many of these entities cannot meet the current IDTF regulations (and cannot enroll in Medicare) because of the indirect nature of their services.

CMS also proposes to exempt such IDTFs from other regulatory requirements outside the construct of an in-person patient interaction and recognizes that these do not make sense for innovative technologies such as digital health or AI systems. We support these changes and appreciate CMS's attention to this issue.

VIII. Comments on Revisions to Open Payments Reporting Requirements

The Proposed Rule would add a definition of "physician-owned distributorship" (or "POD") and require applicable manufacturers and applicable group purchasing organizations that meet the definition to identify their status as PODs when registering or recertifying in Open Payments.[17]

MDMA believes that transparency regarding PODs is important, and shares CMS's concern that many PODS do not report under the Open Payments program. We are concerned that the proposed definition does not address this failure to report, because it does not address the confusion about what entities are required to register and report. At the same time, the definition would require a large segment of traditional medical device makers to self-identify as PODs, even if they have a mere nominal or incidental amount of physician ownership and otherwise lack the characteristics of physician-owned distributorships. The proposal from CMS will not increase transparency with respect to PODs and will impose a significant burden on manufacturers whose ownership and financial relationships do not pose the same inherent conflicts of interest raised by traditional PODs.

[14] Social Security Act § 1848(c)(2)(C), 42 U.S.C. 1395w-4(c)(2)(C).
[15] *Id.* § 1848(c)(6), 42 U.S.C. 1395w-4(c)(6),
[16] *See* 86 Fed. Reg. at 39,313-39,314.
[17] *Id.* at 39,333-39,337.

A. The proposal does not clarify the reporting obligations of PODs.

As CMS notes, the proposed definition of physician-owned distributorship is "a subset of the existing definitions of applicable manufacturer and applicable group purchasing organization." As such, it only applies to entities that are already required to register and report physician ownership payments in the Open Payments system. The proposal is not likely to increase the number of PODs that participate in the Open Payments system, because it does not address confusion about which entities are required to report.

Many PODS arrange for the sale of covered products to a single entity (such as a single hospital or ASC). In order to ensure that these entities are aware of their reporting obligation, it would be helpful to clarify that the term "Applicable Group Purchasing Organization" includes any entity that purchases, arranges for or negotiates the purchase of a covered product for single customer, if the entity has more than one owner, or is otherwise acting for more than one individual or entity (for example, for a supplier or manufacturer). This could be accomplished by amending the definition of applicable group purchasing organization to mean

> "an entity that: (1) Operates in the United States; and (2) Purchases, arranges for or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of individuals or entities, but not solely for use by the entity itself. This definition includes an entity with a single customer, if the entity has more than one owner. It also includes an entity with one or more owners that contracts with more than one customer, or more than one supplier."

B. The proposed definition of PODs is excessively broad and presents a distorted view of manufacturers.

The proposal will not identify or uncover any new PODs. Second, the proposed definition is so broad that it will include many (if not most) privately-held medical device manufacturers, regardless of whether they have any characteristics typically associated with PODs. For instance, the definition proposed by CMS would include any medical device maker with any degree of physician ownership that compensates a physician owner with "a commission, return on investment, profit sharing, profit distribution, or other remuneration directly or indirectly derived from the sale or distribution of devices by the manufacturer."[18] The agency does not indicate what constitutes "other remuneration directly or indirectly derived from the sale or distribution of devices," but if read broadly, this could apply to all sorts of compensation and remuneration for valid, legitimate services that are not related to the sale or marketing of a product. Instead, CMS should hone this language to focus on compensation paid to a physician in exchange for the physician's efforts at selling, marketing, or distributing a product or for using the product in their own patients or facilities, for example, "a commission, return on investment, profit sharing, profit distribution, or other remuneration ***paid to a physician (or his/her immediate family member) as compensation for the physician's (or family member's) efforts to sell, market, or distribute a manufacturer's device, or in proportion to sales of products used by the physician or a medical facility controlled by the physician."***

[18] *See id.* at 39568 (proposed 42 C.F.R. § 403.902) (emphasis added).

Third, the proposal will result in significant confusion, even for those companies that may be required to self-identify as PODs. Within the medical device industry, many sectors have little to no experience with and may not even understand what a POD is. In fact, privately held companies that fall into CMS's broad definition of PODs may be forced to self-identify as such, even if they do not know what a POD is and even if their operations differ vastly from those of a traditional POD.

C. CMS's proposed definition should be narrowed to address PODs' "suspect characteristics."

PODs have been called "inherently suspect"[19] by the U.S. Department of Health & Human Services Office of Inspector General ("OIG"), a point reiterated by the Senate Finance Committee in its 2016 report on PODs.[20] As the Finance Committee report notes, "all PODs are structured to ensure that physician-investors profit from the sale and use of the PODs products that they order for their own patients."[21] OIG even goes as far as elaborating a list of those attributes of PODs that it considers to be "suspect characteristics."[22] Requiring a manufacturer to label itself as a

[19] U.S. Department of Health & Human Services, Office of Inspector General, Special Fraud Alert: Physician-Owned Entities (March 26, 2013), *available at* https://oig.hhs.gov/fraud/docs/alertsandbulletins/2013/POD_Special_Fraud_Alert.pdf (last accessed Aug. 25, 2021) (hereinafter, "OIG Report").

[20] U.S. Senate Finance Committee, Physician Owned Distributorships: An Update on Key Issues and Areas of Congressional Concern, A Senate Finance Committee Majority Staff Report (Feb. 24, 2016), *available at* https://www.finance.senate.gov/imo/media/doc/Combined%20PODs%20report%202.24.16.pdf (last accessed Aug. 25, 2021).

[21] *Id.* at 1.

[22] OIG considers the following to be the suspect characteristics of physician-owned entities:

- The size of the investment offered to each physician varies with the expected or actual volume or value of devices used by the physician.
- Distributions are not made in proportion to ownership interest, or physician-owners pay different prices for their ownership interests, because of the expected or actual volume or value of devices used by the physicians.
- Physician-owners condition their referrals to hospitals or ASCs on their purchase of the POD's devices through coercion or promises, for example, by stating or implying they will perform surgeries or refer patients elsewhere if a hospital or an ASC does not purchase devices from the POD, by promising or implying they will move surgeries to the hospital or ASC if it purchases devices from the POD, or by requiring a hospital or an ASC to enter into an exclusive purchase arrangement with the POD.
- Physician-owners are required, pressured, or actively encouraged to refer, recommend, or arrange for the purchase of the devices sold by the POD or, conversely, are threatened with, or experience, negative repercussions (e.g., decreased distributions, required divestiture) for failing to use the POD's devices for their patients.
- The POD retains the right to repurchase a physician-owner's interest for the physician's failure or inability (through relocation, retirement, or otherwise) to refer, recommend, or arrange for the purchase of the POD's devices.
- The POD is a shell entity that does not conduct appropriate product evaluations, maintain or manage sufficient inventory in its own facility, or employ or otherwise contract with personnel necessary for operations.
- The POD does not maintain continuous oversight of all distribution functions.

POD, even when it lacks "inherently suspect" characteristics of a POD as outlined by OIG, would be burdensome to companies and confusing to patients and customers. Further, recent high-profile enforcement actions have made clear the U.S. Department of Justice's goal of prosecuting PODs.[23] Accordingly, identifying as a POD would also cause significant reputational harm for these companies, as the public is likely to assume that the POD designation indicates an inherently nefarious business model.[24]

Instead of using a broad definition of POD – one that unnecessarily sweeps in virtually all privately-held medical device makers – CMS could add great value to the Open Payments data by incorporating OIG's list of suspect characteristics into its disclosure requirements. For instance, the current Open Payments requirement obligates manufacturers with physician ownership to disclose the "value and terms" of the ownership or investment interest.[25] CMS interprets the "terms" of ownership or investment to mean simply the "type" of ownership or investment interest.[26] In its Open Payments FAQs, CMS states, "[w]hen reporting the terms of an ownership or investment interest, applicable manufacturers . . . should ***report the type of ownership . . . including but not limited to stock, stock options, partnership shares, loans, bonds, or other financial instruments*** . . . ."[27] The type of ownership is not the same thing as the terms of ownership; and disclosure of mere type of ownership interest offers Open Payments users little useful information.

Instead, we recommend that CMS require companies with physician ownership to disclose more and better information about the actual terms of ownership or investment interests – not just the type. CMS could leverage the OIG's suspect characteristics to ask manufacturers and GPOs that disclose ownership interests to identify whether any of the physician ownership or investment interests include the following "terms":

- The size of the ownership or investment interest offered to each physician varies with the expected or actual volume or value of devices used by the physician;

- When a hospital or an ASC requires physicians to disclose conflicts of interest, the POD's physician-owners either fail to inform the hospital or ASC of, or actively conceal through misrepresentations, their ownership interest in the POD.

See OIG Report, *supra* note 2, at 3.

[23] *See, e.g.*, the Asfora Matter (https://www.justice.gov/usao-sd/pr/neurosurgeon-and-two-affiliated-companies-agree-pay-44-million-settle-healthcare-fraud), which also included a settlement with Medtronic (https://www.justice.gov/usao-sd/pr/medtronic-pay-over-92-million-settle-allegations-improper-payments-south-dakota-0), and the Sabit Matter (https://www.justice.gov/opa/pr/detroit-area-neurosurgeon-sentenced-235-months-prison-role-28-million-health-care-fraud).

[24] Although CMS does take steps to note that the definition of PODs for purposes of Open Payments does not apply for purposes of the Stark Law or the Anti-Kickback Statute, this distinction will likely be lost on most users of the Open Payments database. It is also unclear how a federal prosecutor would interpret or apply this language in the course of an enforcement matter. *See* 86 Fed. Reg. at 39335.

[25] 42 C.F.R. § 403.906(b)(5).

[26] Centers for Medicare & Medicaid Services, FAQ 22569, Open Payments FAQs, *available at* https://www.cms.gov/OpenPayments/FAQs (last accessed Aug. 25, 2021).

[27] *Id.* (emphasis added).

- Distributions are made otherwise than in proportion to the physician's ownership interest;

- Physician-owners pay different prices for their ownership interests, because of the expected or actual volume or value of devices used by the physicians;

- Continued ownership is conditioned on physician-owners making referrals to hospitals or ASCs;

- The company requires, pressures or encourages physician-owners to refer, recommend, or arrange for the purchase of the devices sold by the company;

- Physician-owners are threatened with, or experience, negative repercussions (*e.g.*, decreased distributions or required divestiture) for failing to use the company's devices for their patients; and

- The company retains the right to repurchase a physician-owner's interest for the physician's failure or inability (through relocation, retirement, or otherwise) to refer, recommend, or arrange for the purchase of the company's devices.

Using this model, CMS would actually collect information about the terms, and not just the type, of ownership. Companies' disclosures would reveal those practices and behaviors that the government identifies as problematic. It would also provide end users of the Open Payments program with actionable information upon which to make their own conclusions about their providers' independence (or lack thereof).

D. CMS's proposed definition disregards the practicalities of bringing a new product to market.

Under the Proposed Rule, the term "physician owned distributor" applies to all privately-held applicable manufacturers or applicable group purchasing organizations with at least 5% direct or indirect ownership by physicians or their immediate family members (spouse, parents, children, siblings, step-parents, step-siblings, in-laws, grandparents, spouses of grandparents and grandchildren), regardless of whether those physicians (or their family members) order or use the products manufactured by the company, and regardless of whether they received their ownership interest because of their ability to influence the use or purchase of devices. The definition also covers privately-held manufacturers and GPOs with any ownership by a physician or physician's family member who receives remuneration from the manufacturer or GPO that is "directly or indirectly derived from the sale or distribution of devices by the applicable manufacturer or group purchasing organization" without regard to whether the physician is personally involved in the sale, distribution or use of the devices.

There are many reasons that a manufacturer might have owners who are physicians or family members of physicians, none of which relate to sales and marketing schemes or inducing physicians to use or order the manufacturer's products. Many innovative medical technologies are developed by companies founded by physician-inventors. Physicians or their family members often invest in early-stage medical technology companies on the same terms as non-physician investors, typically long before commercialization, and often before the company is able to attract

venture capital investors. Innovative start-up companies may have minimal cash to pay for critical consulting services. Instead, they may issue equity compensation to key consultants, including physician advisors, in these early stages. Companies may also provide equity compensation to key employees or advisors who are not physicians, but who happen to have physician spouses, parents, children, siblings, step-parents, step-siblings, in-laws, grandparents, spouses of grandparents and grandchildren. Under the proposed definition these companies would likely be classified as PODs, simply because an employee or advisor is a licensed physicians or has a family member (even someone as far removed as an estranged step-sibling) that is a licensed physician.

Put more starkly, these entities would be required to identify themselves as PODs even if:

- The physician owners receive their equity on the same terms as other investors or employees;
- The physician owners have no involvement in any aspect of sales or marketing of products;
- The physicians are not currently practicing medicine or practice in an area unrelated to the company's medical technology; and
- The company did not know when issuing the ownership interest that the recipient was a physician or had a relative who was a physician.

Any definition of POD should focus on entities with significant physician ownership that derive a substantial portion of their revenue from sales to customers affiliated with their physician-owners. This approach would not reduce transparency with respect to physician owners in applicable manufacturers that are not PODs, since they are already required to report ownership by physicians and their immediate family members, as well as payments to physicians. Rather, it would avoid confusion by ensuring that the POD designation only applies to entities that have the fundamental characteristics associated with PODs.

Conclusion

Thank you for the opportunity to provide comments on the CY 2021 PFS proposed rule. MDMA looks forward to working with CMS as it develops the final rule. If we can be of any further assistance, please contact me at mleahey@medicaldevices.org or (202) 354-7171.

Sincerely,

Mark Leahey
President and CEO
Medical Device Manufacturers Association