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December 30, 2019

[Submitted electronically via www.regulations.gov]

Joanne Chiedi, Acting Inspector General
Office of Inspector General
Department of Health and Human Services
Attention: OIG-0936-AA10-P
Room 5521, Cohen Building
330 Independence Avenue SW, Washington, DC 20201

Re: Medicare and State Healthcare Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, Proposed Rule (RIN 0936-AA10)

Dear Acting Inspector General Chiedi:

Our organizations are pleased to submit these comments regarding the Office of Inspector General (“OIG”), Department of Health and Human Services (“HHS”) proposed rule, “Medicare and State Healthcare Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements” (hereinafter the “Proposed Rule”).

APhA, founded in 1852 as the American Pharmaceutical Association, represents 60,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, physicians’ offices, hospitals, specialty pharmacies, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services.

The National Alliance of State Pharmacy Associations (“NASPA”), founded in 1927 as the National Council of State Pharmacy Association Executives, is dedicated to enhancing the success of state pharmacy associations in their efforts to advance the profession of pharmacy. NASPA’s membership is comprised of state pharmacy associations and over 70 other stakeholder organizations. NASPA promotes leadership, sharing, learning, and policy exchange among its members and pharmacy leaders nationwide.

Our organizations applaud the efforts of OIG, in conjunction with CMS, for advancing HHS' "Regulatory Sprint to Coordinated Care," by adding three new safe harbors for value-based arrangements that may include clinicians, providers, suppliers and others. As we understand, the following three proposed new safe harbors aim to foster better coordinated patient care:

- (i) Care coordination arrangements to improve quality, health outcomes, and efficiency;
- (ii) Value-based arrangements with substantial downside financial risk; and
- (iii) Value-based arrangements with full financial risk.

In addition, OIG proposes safe harbors to protect certain arrangements for patient engagement tools and supports and expansion of the current safe harbor related to electronic health record services.

Although pharmacists are not eligible for direct reimbursement under Medicare Part B, current value-based models, such as accountable care organizations ("ACOs") have greater ability to sustain pharmacists. These value-based models harness pharmacists' services to improve different aspects of care, including medication adherence, chronic care management and care coordination, which are not supported by the current fee-for-service system. As OIG finalizes the Proposed Rule, we urge pharmacists be recognized like other health care providers (e.g., physician assistants, nurses) who provide meaningful patient care services. To assist OIG's efforts, we offer the following comments on the Proposed Rule and to serve as a resource to HHS on the current role of pharmacists in value-based arrangements and the potential for greater integration of pharmacists into patient-care teams which will contribute to the type of beneficial VBEs this rulemaking is designed to cultivate.

OIG – CMS Collaborative Rulemaking

We are submitting formal comments to OIG as the Federal Anti-Kickback Statute ("AKS") (42 U.S.C. § 1320a-7b(b)) applies directly to pharmacists and all other medical providers in a position to arrange or recommend items or services reimbursed by federal health care programs. Although the physician self-referral law or Stark Law (42 U.S.C. § 1395nn) applies only to relationships with physicians, given the inter-connected nature of this Proposed Rule and the Stark Law proposed rule, we are also submitting these comments in response to the Centers for Medicare and Medicaid Services ("CMS") "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations (CMS-1720-P)." We appreciate OIG's intent to align proposed value-based terminology with the proposals provided for by CMS in the Stark Law Proposed Rule, but encourage OIG to reiterate our concerns in communications with CMS as we do not address the variations in terminology and definitions. Our organizations support a clear regulatory framework that includes pharmacists and pharmacies in value-based models and other modern business relationships.

Opportunities for Value-Based Enterprises (VBE) to Utilize Pharmacists

Our organizations support OIG’s agnostic approach regarding the composition of a value-based enterprise (“VBE”) and indicating that ACOs may be a VBE.¹ As HHS understands, collaborative care models that include a pharmacist can help alleviate the demand for physician-provided care and improve care coordination. As new payment and delivery models (e.g., ACOs and patient-centered medical homes (“PCMHs”)) proliferate, new roles exist for pharmacists to contribute to the improvement of quality of patient care, health outcomes and the reduction of costs for health care services by improving the efficiency of delivered health care services. A number of ACOs currently integrate pharmacists for medication management and other services. Examples of these direct patient care services provided by pharmacists include pharmacist initiation (prescribing), immunizations, wellness and prevention screening, chronic care management, and patient education and counseling.

Our nation’s health care delivery system is evolving rapidly and providers, including pharmacists, are focused on delivering higher value services, with an increasing appreciation of coordinated care and an interdisciplinary team approach that extends beyond institutional walls. As part of this modernization, research has shown coordinated care models involving a range of health care practitioners, including pharmacists, are essential for realizing the maximum impact of patient care delivery.³ For example, a recent study of pharmacist involvement in transitional care management at the University of North Carolina found that hospital readmission rates and interventions in a multidisciplinary team visit coordinated by a clinical pharmacist practitioner vs. physician-only team had a 30-day readmission rate of 14.3% compared with 34.3% by the physician-only team, where there was also statistical significance addressing nonadherence, initiating a new medication and discontinuing a medication.⁴

Moving forward, the development of new value-based arrangements, including pharmacogenomic (PGx) testing and subsequent interpretation to provide personalized medicine (prescribing and care plans) and other innovations, will advance only if permitted by OIG’s and CMS’ regulatory framework. However, for these new models to succeed, pharmacists will need to be adequately compensated for their contributions and expanded role in the health care team, either through attributable portions of shared savings or separate permissible contractual agreements with ACOs or other payors that guarantee revenue for their services. OIG, working collaboratively with CMS to assure compliance with Stark law, can provide the clarity and flexibility necessary for VBEs to ensure these payment arrangements for pharmacist-provided patient care services are permissible under the AKS. These clarifications would increase the pharmacists and other clinicians engaging in, and patients benefitting from, pharmacist-provided patient care services in value-based arrangements.

¹ 84 FR [55723](#)

³ Mitchell, Pamela. Et. al. Core Principles & Values of Effective Team-Based Health Care. Institute of Medicine. October 2012, available at: <https://www.nationalahec.org/pdfs/VSRT-Team-Based-Care-Principles-Values.pdf>

⁴ Cavanaugh, JJ. Et. al. Pharmacist-coordinated multidisciplinary hospital follow-up visits improve patient outcomes. J Manag Care Spec Pharm. 2015 Mar;21(3):256-60, available at: <https://www.ncbi.nlm.nih.gov/pubmed/25726034>

VBE's Assumption of Downside Financial Risk (Pg. 55702)

As OIG indicates, these proposed safe harbors vary by the types of remuneration protected (in-kind or in-kind and monetary), the level of financial risk assumed by the parties, and the types of safeguards included as safe harbor conditions. These changes, if allowed to flourish, will remove outdated regulatory barriers to incentivize new payment and delivery models (e.g., team based care models including pharmacists and pharmacies) to improve the quality of patient care, health outcomes, and efficiency of our nation's health care delivery system.

As noted above, two of the three proposed safe harbors for value-based arrangements require a VBE to assume downside financial risk from a payor. While our organizations acknowledge advantages can result from increasing ACOs and other alternative payment models' ("APMs") downside financial risks, such as facilitating value-based purchasing, we are aware of challenges ACOs and other advanced APMs have faced when deciding to accelerate risks. We are concerned these issues will also arise for VBEs or discourage potential "VBE Participants" from engaging in a "value-based activity." Therefore, we suggest OIG provide flexibility regarding the degree of downside financial risk a VBE will be required to assume to meet the safe harbor.

As OIG considers our request regarding risk assumption, we encourage consideration of feedback from pharmacists. While a number of pharmacists already participate in the advanced Next Generation ACO models, many of these models are in closed health care systems with established infrastructure(s) and greater control over the health care services provided to their attributed beneficiaries. As a result, pharmacists have indicated that their ACOs are considering becoming Medicare Advantage (MA) plans because MA plans may request Advanced APM status for certain provider contracts without downside financial risk. Although, we appreciate and support variable models and types of networks, certain factors impact ACOs' and other value-based arrangement models' ability to assume risk, particularly for those with shared savings and multiple contracted providers. Because there is still a significant amount of provider and beneficiary education needed on two-sided risk models, our organizations recommend OIG work with CMS to also pilot the new AKS safe harbors with varying levels of risk utilizing team-based care models that include pharmacists to better understand implications, including practitioner responses, to VBE participation and subsequent shifts in risk.

Entities Not Included as VBE Participants (Pgs. 55703-55706)

a. Laboratories

As our nation's health care system continues to move towards personalized medicine to optimize health outcomes and reduce unnecessary costs, we urge OIG to allow Clinical Laboratory Improvement Amendments of 1988 ("CLIA"-certified) laboratories to qualify as a "VBE participant" in value-based payment arrangements that provide PGx testing as well as the health care practitioners interpreting these test results for clinical applications under the new AKS safe harbors. Studies estimate genetic screening in the primary care setting may be the

future of preventative medicine.⁵ If wielded productively, it can provide vital data to help predict hereditary disease contraction as well as provide time to plan for care if a detrimental genetic disease such as Tay Sachs, Alzheimer's disease, or Down syndrome, is confirmed in patients.^{6,7} In recent years the introduction of genetic screening via primary care has ultimately led to the prevention of and heightened quality of treatment for several familial diseases in countless cases.⁴

Currently, the Proposed Rule expressly excludes “laboratories” as a “VBE participant” from the new AKS safe harbors. OIG states it is concerned the safe harbors will be used “...primarily as a means of offering remuneration to practitioners and patients to market their products, rather than as a means to create value for patients and payors by improving the coordination and management of patient care, reducing inefficiencies, or lowering health care costs.” OIG states these arrangements “...tether clinicians or patients to the use of a particular product...when a different product could be more clinically effective for the patient.” In addition, that “...laboratories are less likely to be on the front line of care coordination and treatment decisions in the same way as other types of proposed VBE entities, such as hospitals, physicians, and remote monitoring companies that provide care coordination and management tools and services directly to patients.” Our organizations hope to correct/clarify these assumptions as they would unintentionally restrict the use of PGx laboratory testing in value-based payment arrangements by triggering the AKS.

PGx laboratory testing is generally required to integrate PGx into clinical practices to benefit patients. However, there is variable coverage for PGx tests and related services. While the laboratories themselves are not “on the front line of care coordination,” pharmacists and other clinicians who interpret the results of PGx laboratory tests are and can apply them to formulate individual patient care plans. As health care becomes more personalized, pharmacists and other practitioners need to receive and interpret the results of PGx tests, with attributable remuneration for these services, to create the best individualized patient care plan based on this information to effectively and efficiently coordinate patient care. As the medication experts, a PGx-trained pharmacist can work hand-in-hand with the ordering provider to interpret PGx laboratory results, combined with several other clinical factors for each individual patient to reduce cost and potentially even save lives through more effective personalized prescribing. In addition, there are a variety of different labs and PGx tests to provide choice and competition for providers and patients rather than tying them to a particular product.

As HHS is aware, pharmacist-provided patient care services are not currently covered by Medicare Part B but are covered by other payers, including several Medicaid programs. Our organizations strongly agree with several of the Administration’s recommendations in the recent report “Reforming America’s Healthcare System Through Choice and Competition,” including the recommendation to allow pharmacists and other health care providers to practice to the top of their license, utilizing their full skill set and training. Further, the report encourages the federal

⁵ Sandler, Sierra. Et. al. The importance of preventative medicine in conjunction with modern day genetic studies. *Genes Dis.* 2018 Jun; 5(2): 107–111, available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6146230/#bib15>

⁶ Kaback M.M. Population-based genetic screening for reproductive counseling: the Tay-Sachs disease model. *Eur J Pediatr.* Dec 2000;159(3):S192–S195, available at: <https://www.ncbi.nlm.nih.gov/pubmed/11216898>

⁷ Levy H.L., Albers S. Genetic screening of newborns. *Annu Rev Genomics Hum Genet.* Sep 2000;1(1):139–177, available at: <https://www.ncbi.nlm.nih.gov/pubmed/11701628>

government to consider administrative proposals to allow nonphysician providers, including pharmacists, to be paid directly for their services.⁸ Similarly, we support the Administration's October 2019 Executive Order proposing a HHS regulation that would eliminate "burdensome regulatory billing requirements, conditions of participation, supervision requirements, benefit definitions, and all other licensure requirements of the Medicare program that are more stringent than applicable Federal or State laws require and that limit professionals from practicing at the top of their profession."⁹ However, until such clarifications are made through regulatory or legislative means, pharmacists and other practitioners interpreting the results from PGx laboratory tests may have to be paid by laboratories or under other payment arrangements which will require OIG clarification that these arrangements do not violate the AKS.

The Clinical Pharmacogenetics Implementation Consortium ("CPIC") has published genotype-based drug guidelines to help clinicians understand how available genetic test results could be used to optimize drug therapy. The key underlying assumption for all CPIC guidelines is that clinical high-throughput and pre-emptive genotyping will eventually become common practice and clinicians will increasingly have patients' genotypes available before a prescription is written.¹⁰ New health care delivery and payment models already exist to allow clinicians to make patient care decisions for specific drugs when genetic results are available. In addition, electronic health records ("EHRs") and clinical decision support ("CDS") will play much more of an essential role for implementation of PGx. Accordingly, in order to allow PGx testing to be incorporated into new value-based payment arrangements geared toward maximizing the benefits of genetic information for personalized and individual patient care, we urge OIG to allow CLIA-laboratories conducting PGx testing, as well as the health care practitioners interpreting PGx results, and the related remuneration under these arrangements, to qualify for new AKS safe harbors as a "VBE participant."

Lastly, we note that a pharmacy is included as a "laboratory" under CLIA, however, a pharmacy may possess a CLIA Certificate of Waiver so that they may expand patient access to CLIA-waived tests and improve public health. For example, patients may come to a pharmacy with a Certificate of Waiver to obtain a CLIA-waived point-of-care ("POC") test for an infectious disease. One recent study involved pharmacists in three states, where pharmacists in waived pharmacies worked with a physician under a collaborative practice agreement to help identify patients for an influenza POC test and subsequent identification and management of patients who tested positive for influenza.¹¹ This type of model helps earlier identify patients with infectious conditions as several of those screened did not have a primary care provider or were seen outside of regular clinic office hours. However, the ability to recoup both the costs associated with the CLIA-waived test and the pharmacist's time is essential for these models to

⁸ U.S. Departments of HHS, the Treasury, and Labor. Reforming America's Healthcare System Through Choice and Competition. November 30, 2018, available at: <https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf>

⁹ The White House. EO 13890: Protecting and Improving Medicare for Our Nation's Seniors. October 3, 2019. Available at: <https://www.federalregister.gov/documents/2019/10/08/2019-22073/protecting-and-improving-medicare-for-our-nations-seniors>

¹⁰ Caudle, Kelly. Et. al. Incorporation of Pharmacogenomics into Routine Clinical Practice: the Clinical Pharmacogenetics Implementation Consortium (CPIC) Guideline Development Process. *Curr Drug Metab.* 2014 Feb; 15(2): 209–217. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3977533/>

¹¹ ME Klepser, et al. Effectiveness of a pharmacist-physician collaborative program to manage influenza-like illness. *J Am Pharm Assoc.* 2016; 56:14-21, available at: <https://www.ncbi.nlm.nih.gov/pubmed/26802915>

advance but are a significant barrier currently.¹² Therefore, we recommend OIG, working collaboratively with CMS, adopt regulations that support collaborative care models involving pharmacies with a CLIA Certificate of Waiver and pharmacist-provided care.

b. Pharmacies as Distributors, or Suppliers of DMEPOS

Our organizations urge OIG to include CMS-accredited pharmacy distributors/ suppliers of DMEPOS that provide services and products that contribute towards value-based activities as “VBE participants” under any new AKS safe harbors for VBEs. OIG is considering for the final rule whether distributors, or suppliers of DMEPOS should also be excluded as a “VBE participant” and if this exclusion should apply only to independent or free-standing DMEPOS suppliers and to DMEPOS suppliers owned or operated in whole or part by another entity excluded as a VBE participant. As OIG understands, CMS mandates suppliers of DMEPOS attain accreditation, such as from the National Association of Boards of Pharmacy (“NABP”), to obtain or maintain Medicare billing privileges for providing reliable and cost-effective services. Many patients often require the benefits of both pharmacies and DMEPOS. For example, a typical piece of DME, such as a nebulizer, is essentially useless until that person receives medication, such as duoneb or albuterol, from a licensed pharmacy provider to put in that nebulizer. Clearly, DMEPOS pharmacies could easily play a role, (e.g., in this example for asthmatics), acting as a “VBE participant” by providing the products, medications and pharmacist-provided patient counseling services under a value-based payment model to effectively and efficiently coordinate patient care. For example, a pharmacist at a DME pharmacy supplying home infusion that provides external infusion pumps and supplies could also routinely provide a number of professional services such as drug therapy evaluation and design, drug preparation and compounding, care planning, care coordination, monitoring services and remote monitoring.

c. Retail and Community Pharmacies

Our organizations strongly urge OIG to clarify that retail and community pharmacies participating in value-based arrangements qualify for these new safe harbors as a “VBE participant.” Under the Proposed Rule, OIG is seeking comments on beneficial arrangements for pharmacies to participate under the new safe harbor protection under the value-based framework and any safeguards for the final rule. OIG states “[w]e acknowledge that some pharmacies (and pharmacists) have the potential to contribute to the type of beneficial value-based arrangements this rulemaking is designed to foster (e.g., through medication adherence programs or educational services for patients with diabetes).” However, OIG is also considering excluding pharmacies (e.g., specific types of pharmacies) from qualifying as a “VBE participant” due to concerns their participation in value-based arrangements may not further care coordination. The role of pharmacists at pharmacies and other sites of care has evolved beyond simply providing “items,” or functioning as medication dispensers.¹³ While nearly all pharmacies in America use Certified Pharmacy Technicians to assist in prescription preparation and hand prescription

¹² See, Burley, E., Klepser, S. & Klepser, M. (2014). Opportunities for Pharmacists to Improve Access to Primary Care Through the Use of CLIA-waived tests. *Michigan Pharmacists Association*, 52(2), available at: <https://www.michiganpharmacists.org/Portals/0/resources/poctest/poctest0414.pdf>, last accessed, December 27, 2019.

¹³ Avalere. Exploring Pharmacists’ Role in a Changing Healthcare Environment. May 21, 2014, available at: <https://avalere.com/insights/exploring-pharmacists-role-in-a-changing-healthcare-environment>

medications to patients, others use mail carriers. All pharmacies use pharmacists—and only pharmacists to evaluate prescriptions and provide patient counseling, and often to each others' patients. Community pharmacy is about much more than pills in a bottle. Today, community pharmacists practicing at community pharmacies are taking an active role in patient care with a focus on improving patient outcomes where our members:

- Counsel patients on drug interactions, side effects, safety, and efficacy of the medications they take.
- Initiate or prescribe medications, such as lifesaving naloxone,¹⁴ which the Centers for Disease Control (“CDC”) proves has contributed to lowering deaths.¹⁵
- Advise patients on how to use over-the-counter (“OTC”) medications and supplements safely and effectively, often in conjunction with prescriptions.
- Hold conversations with patients on how to best take a medication and why the medication is important.
- Evaluate medication histories and catch potentially serious dosing and interaction problems.
- Counsel on managing chronic conditions.
- Provide lifesaving immunizations to patients (often without an appointment).
- Work with the patient’s physicians to coordinate care and clarify, adjust, and advise regarding therapy, and to help problem solve when patients can’t afford their medications.

In addition, community pharmacies are handling dramatically increased prescription volumes by adopting enhanced technology, employing and training highly qualified technicians, and adopting systems to identify opportunities for assisting prescribers in recognizing opportunities to optimize therapies. In short, pharmacists practicing at pharmacies in America are focused on a lot more than accurate dispensing (i.e., “providing items” as mentioned in the Proposed Rule) and making difficult calls to prescribers. Below, is just one example of pharmacists’ participation in value-based payment arrangements whose benefits and cost savings should be expanded under OIG’s new safe harbor protections:

- A pharmacist-led transition of care program in California significantly reduced readmissions and health care costs in managed Medicaid populations. The model showed that one transition of care program was cost saving at over \$3 per member per month in the first 6 months, which translates to over \$25 million in total health care cost savings over 2 years.¹⁶ Another model at a hospital pharmacy for a Medicaid managed care plan, resulted in total health care costs at 180 days after discharge at an average of \$2,139 lower than costs in the control group, yielding

¹⁴ OIG could also clarify that pharmacists prescribing naloxone could allow patients to fill this prescription at that same pharmacies without violating AKS. We have heard anecdotal evidence that sending patients to other pharmacies may create access issues if patients do not fill these prescriptions at pharmacies where they receive prescriptions. See, NASPA. Pharmacist Prescribing: Naloxone. January 17, 2019, available at: <https://nasp.us/resource/naloxone-access-community-pharmacies>.

¹⁵ CDC. Life-Saving Naloxone from Pharmacies. More dispensing needed despite progress. Last reviewed: August 6, 2019, available at: <https://www.cdc.gov/vitalsigns/naloxone/index.html>

¹⁶ Weiyi, Le. Et. al. Budget Impact Analysis of a Pharmacist-Provided Transition of Care Program. Journal of Managed Care and Specialty Pharmacy. Volume 24 Issue (2). J Manag Care Spec Pharm, 2018 Feb;24(2):90-96. <https://doi.org/10.18553/jmcp.2018.24.2.90>.

estimated savings of nearly \$1.8 million for the managed care plan.¹⁷ The same pharmacy solutions team is in an evaluation of a pharmacist-led transition of care program for an ACO (at-risk physicians group). Preliminary results are showing that the implementation of the program had a significant impact on reducing hospital readmission rates over time. In order to initiate these models under current AKS and Stark laws the clinical pharmacists in these arrangements provided transition of care and coordinated patient-care services completely separate from their participation in community pharmacies, which restricts access to additional patients at their pharmacies who could also benefit from these services and savings. Accordingly, we urge OIG to unlock these proven savings and reductions in unnecessary admissions by allowing pharmacists to also offer these services to patient populations at their practicing pharmacies.

d. Compounding Pharmacies

Similarly, pharmacists at compounding pharmacies can play a significant role in helping to coordinate individualized patient care and should not be excluded from an AKS safe harbor for the services they provide as a “VBE participant” to patient care teams under value-based arrangements. Under the Proposed Rule, compounding may play a key role as value-based activities must be tailored to meet the needs of a defined patient population to improve health outcomes or lower costs (or both). Many members of this “defined population” may require customized compounded medications. Simply excluding participating compounding pharmacies from the safe harbor would expose these pharmacies to the AKS for any remuneration they receive for providing prescription compounded medications or pharmacist-provided patient care services if they are not included as a “VBE participant.” Additionally, depending on the level of downside risk, any pharmacy, including any compounding pharmacy, would be responsible for meeting its goals under any approved value-based activity under VBE’s evidence-based outcomes measures.

To clarify for OIG, compounding is the preparation of a specific medication to meet the prescriber’s exact specifications and to be dispensed directly to an individual patient, pursuant to a valid prescription for that patient. Compounding should not be confused with manufacturing or the mass production of drug products. Compounding also does not include making copies of commercially available drug products, as this is not allowed by law. A health care provider will prescribe a compounded drug only when commercially available drug products do not meet patient needs. Following are a few examples of how a compounding pharmacist can customize medications based upon a physician’s prescription to meet a patient’s needs:

- Customize strength or dosage.
- Flavor a medication (to make it more palatable).
- Reformulate the drug to exclude an unwanted, nonessential ingredient, such as lactose, gluten, or a dye to which a patient is allergic.

¹⁷ Weiyi, Le. Et. al. Reduction of healthcare costs through a transitions-of-care program. American Journal of Health-System Pharmacy, Volume 75, Issue 10, 15 May 2018, Pages 613–621, <https://doi.org/10.2146/ajhp170255>

- Change the form of the medication for patients who, for example, have difficulty swallowing or experience stomach upset when taking oral medication.

e. Pharmacy Benefit Managers (“PBMs”)

Our organizations strongly agree with OIG’s proposed exclusion of PBMs from any new safe harbors under the AKS statute. Under the Proposed Rule, OIG is also considering “excluding pharmacy benefits managers (PBMs), wholesalers, and distributors from the definition of “VBE participant” for reasons comparable to those for excluding pharmaceutical manufacturers.” As OIG outlined in its recent proposed rule “Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager (PBM) Service Fees,”¹⁸ there are serious concerns for abuse under current PBM practices. PBMs were only originally formed to alleviate administrative burden and process prescription drug claims cheaper and faster than insurance companies. However, PBMs’ role has evolved to negotiating prices with drug companies, offering rebates when drugs were included in insurance formularies and implementing Medicare’s Part D prescription drug program. As a result, PBM practices have led to increases in patient’s drug prices at the pharmacy counter through utilization of direct and indirect remuneration (DIR) fees, delaying prescribed treatments through patient steering and prior authorization, and limiting options for patients by controlling access to insurance networks. These common PBM practices alone warrant adding them to OIG’s exclusion list due to their significant increases in the risk for fraud and abuse under the AKS statute. In addition, while PBMs are not health care clinicians or providers, they are increasingly determining services related to the coordination of care for patients at an alarming rate, which is disrupting the triad of the physician-pharmacist-patient relationship. Furthermore, all the top PBMs are either owned by, or own an insurance company and are no longer ‘third party’ providers. Practitioners often give the analogy if your car mechanic was owned by your car insurance company, then getting your car fixed after an accident would become a challenge – skimping on the repairs helps them both. Accordingly, due to the vertical integration of PBMs and their highly questionable practices, which are clearly ripe for abuse, our organizations urge OIG to work with CMS to include this exclusion in both agencies’ final rules.

Waiver or Reduction of Cost-Sharing Obligations (Pgs. 55725-55726)

Our organizations also support OIG creating a safe harbor for “patient engagement and support to improve quality, health outcomes, and efficiency” for VBEs, including ACOs as this is similar to the current CMP exemptions allowed for the waiver of cost sharing amounts found at section 1128A(i)(6)(A) and 42 CFR 1003.110. Under the Proposed Rule, OIG is interested in comments that identify potential benefits of permitting in the final rule the waiver or offset of cost-sharing obligations as part of a value-based arrangement under a value-based framework. Multiple studies have found that people who had to pay more for services at point-of-service were considerably less likely to seek medical care, which also have the tendency to cause more

¹⁸ OIG. Fraud and Abuse: Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees. February 6, 2019. Available at: <https://www.regulations.gov/document?D=HHSIG-2019-0001-0001>

harm to racial and ethnic minorities than to others.¹⁹ Our members have expressed an interest in creating ACO/ VBE models that would reimburse pharmacies for the copayment requirement for medications or allow pharmacies to offer copayment forgiveness. Removing this financial barrier could have a significant impact on improving beneficiary access and adherence to necessary medications and will also help drive reductions in hospitalizations and avoidable medical expenditures in other parts of the Medicare program. This point is reinforced by the fact that the United States spends \$528 billion annually on medication-related issues.²⁰ As stated under the Proposed Rule, while cost-sharing is required pursuant to statute and regulations set forth by CMS, ACOs and participating pharmacies are now required to enforce the copayment requirement or face a penalty. On a daily basis, our members encounter beneficiaries who often choose not to fill a prescription for a necessary medication due to the copayment requirement, which results in these patients going to the hospital for untreated conditions. Often ACOs are also responsible for the hospital care these patients have to incur for these avoidable increased health care costs which impedes their abilities to meet CMS' requirements for improving quality and reducing cost. Creating an AKS safe harbor to protect these arrangements would incentivize the creation of more ACOs by alleviating the penalties faced by hospitals under these arrangements for patients not taking or receiving their medications as well as improving the health of participating beneficiaries.

Our organizations also support OIG creating a safe harbor for ACOs, discussed in the Proposed Rule, who, acting as VBEs, would share the savings that patients help generate for the ACO as a payer to offset cost-sharing obligations. For example, a patient, working with a pharmacist and other members of their care team, who selects a clinically appropriate but less costly medication, producing savings for the ACO. ACO models could easily be established to where patient-generated savings from utilizing generic or other clinically appropriate medications could be used to reduce ACO participant copayments.

Electronic Health Records (1001.952(y)) (Pgs. 55739-55744)

Our organizations support the Pharmacy Health Information Technology Collaborative's comments on the Proposed Rule regarding Electronic Health Records Items and Services (§411.357(w)) on Interoperability (The "Deeming" Provision) and Information Blocking and Data Lock-in (§411.357(w)(3)) (Cybersecurity and Definitions).

While we generally support eliminating or reducing the percentage contribution required for small or rural practices under the EHR safe harbor rule, our organizations request OIG only grant safe harbor protection to donors of EHRs that provide access to pharmacists in order to maximize coordinated care efforts which are necessary to align with current MACRA regulations

¹⁹ Rice, Thomas. The impact of cost containment efforts on racial and ethnic disparities in health care: a conceptualization. *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care*. Institute of Medicine (US) Committee on Understanding and Eliminating Racial and Ethnic Disparities in Health Care; Smedley BD, Stith AY, Nelson AR, editors. Washington (DC): National Academies Press (US); 2003, available at: <https://www.ncbi.nlm.nih.gov/books/NBK220345/>

²⁰ Watanabe, J.H., McInnis, T. & Hirsch, J.D. (2018). Cost of Prescription Drug-Related Morbidity and Mortality, *Annals of Pharmacotherapy*, available at: <https://doi.org/10.1177/1060028018765159>

and other, existing statute.^{21,22} Pharmacists are frequently blocked from the exchange of relevant clinical information with other health care providers using health information technology. Such restrictions impede the ability of CMS and patients to benefit from coordinated, team-based care.

Finally, our organizations believe an additional safe harbor should be created, if necessary, to clarify that a pharmacist / pharmacy as a “VBE participant” could pay (provide remuneration) to access /plug into a EHR network to share information with a hospital/ health system or a hospital/ health system could provide this access as remuneration to pharmacies under a value-based arrangement without triggering the AKS in order to coordinate patient care.

Thank you for the opportunity to provide feedback on the Proposed Rule and consideration of our comments. Our organizations welcome the opportunity to serve as a resource to HHS and can provide OIG and CMS access to pharmacists who are currently participating in value-based payment arrangements. If you have any questions or require additional information, please contact, Michael Baxter, APhA Director of Regulatory Affairs, at mbaxter@aphanet.org or (202) 429-7538 and Allie Jo Shipman, PharmD, MBA, NASPA Director of State Policy, at ajshipman@naspa.us or (803) 257-1818.

Sincerely,

American Pharmacists Association (APhA)
National Alliance of State Pharmacy Associations (NASPA)
Alabama Pharmacy Association
Arizona Pharmacy Association
Arkansas Pharmacists Association
California Pharmacists Association
Colorado Pharmacists Society
Connecticut Pharmacists Association
Florida Pharmacy Association
Georgia Pharmacy Association
Idaho State Pharmacy Association
Illinois Pharmacists Association
Indiana Pharmacists Association
Iowa Pharmacy Association
Kansas Pharmacists Association
Kentucky Pharmacists Association
Maryland Pharmacists Association
Michigan Pharmacists Association
Minnesota Pharmacists Association

²¹ See, 81 Fed. Reg. 77030 which states “A health care provider must attest that it implemented technologies, standards, policies, practices, and agreements reasonably calculated to ensure, to the greatest extent practicable and permitted by law, that the certified EHR technology was, at all relevant times: . . . (4) implemented in a manner that allowed for the timely, secure, and trusted bi-directional exchange of structured electronic health information with **other health care providers (as defined by 42 U.S.C. 300jj(3))**, including unaffiliated health care providers, and with disparate certified EHR technology and vendors,” available at: <https://www.gpo.gov/fdsys/pkg/FR-2016-11-04/pdf/2016-25240.pdf>

²² See, 42 U.S.C. 300jj(3) defining health care provider as “The term “health care provider” includes a hospital, skilled nursing facility, nursing facility, home health entity or other long term care facility, health care clinic, community mental health center (as defined in section 300x–2(b)(1) of this title), renal dialysis facility, blood center, ambulatory surgical center described in section 1395I(i) of this title, [1] emergency medical services provider, Federally qualified health center, group practice, **a pharmacist, a pharmacy** . . . and any other category of health care facility, entity, practitioner, or clinician determined appropriate by the Secretary,” available at: <https://www.law.cornell.edu/uscode/text/42/300jj>

Mississippi Pharmacists Association
Missouri Pharmacy Association
Nebraska Pharmacists Association
New Jersey Pharmacists Association
New Mexico Pharmacists Association
North Carolina Association of Pharmacists
North Dakota Pharmacists Association
Ohio Pharmacists Association
Oklahoma Pharmacists Association
Oregon State Pharmacy Association
Pennsylvania Pharmacists Association
Pharmacists Society of the State of New York
Pharmacy Society of Wisconsin
South Carolina Pharmacy Association
South Dakota Pharmacists Association
Tennessee Pharmacists Association
Texas Pharmacy Association
Utah Pharmacy Association
Vermont Pharmacists Association
Virginia Pharmacists Association
Washington State Pharmacy Association
West Virginia Pharmacists Association

cc: The Honorable Alex Azar II, Secretary, HHS
The Honorable Seema Verma, Administrator, CMS