



June 27, 2016

[Submitted electronically via www.regulations.gov]

Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-5517-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare Program; Merit-Based Incentive Payment System and Alternative Payment Model Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models; Proposed Rule

The undersigned pharmacy organizations would like to thank the Centers for Medicare and Medicaid Services (“CMS”) for the opportunity to comment on the Proposed Rule for the Medicare Program; Merit-Based Incentive Payment System and Alternative Payment Model Incentive under the Physician Fee Schedule (“PFS”), and Criteria for Physician-Focused Payment Models (the “Proposed Rule”). Collectively, our organizations represent over 100,000 pharmacists across the full spectrum of practice settings.

The Medicare Access and CHIP Reauthorization Act of 2015 (“MACRA”) (Public Law 114-10) repeals the Medicare sustainable growth rate (“SGR”) payment methodology for updates to the physician fee schedule (“PFS”) and replaces it with a new Merit-based Incentive Payment System (“MIPS”) for MIPS eligible clinicians or groups. The Proposed Rule, if finalized, would implement the MIPS program and incentives for participation in certain alternative payment models (“APMs”). It would also add new criteria for use by the Physician-Focused Payment Model Technical Advisory Committee (“PTAC”) in making comments and recommendations to evaluate physician-focused payment models (“PFPMs”). Our organizations applaud CMS’s continuing efforts to transition 50% of Medicare payments into APMs by the end of 2018.¹ CMS reinforces this commitment through the Proposed Rule by promoting value-based payment models for physicians with incentives for high quality, cost-effective care. Coordinated care models utilizing other health care practitioners, such as pharmacists, are essential for realizing the maximum impact of team-based care². As vital members of patients’ health care teams, our organizations and our members strongly believe that better integration of pharmacists into Medicare, including the addition of pharmacists as “eligible clinicians” under MIPS and advanced APMs, is necessary to achieve the underlying statute’s goals “to develop a program that is meaningful, understandable, and flexible for participating clinicians” and “design incentives that drive delivery system reform principles and participation in APMs.”

To align with CMS’s transition to value-based payments, our comments focus on removing barriers to pharmacist participation in Medicare; recognizing pharmacists and other health care providers’ contributions in quality and clinical practice improvement activity (“CPIA”) performance measurement; urging CMS to include or support the inclusion of pharmacist representation on the PTAC and in prioritization of new PFPMs; and improving clinical information exchange between pharmacists and physicians and other health care practitioners.

I. Removing Barriers Preventing Pharmacists’ Inclusion in Medicare (p. 28293)

Our organizations appreciate CMS not only recognizing the value of team-based care, but encouraging its adoption throughout the Proposed Rule. CMS provides in the Proposed Rule’s *Overview of Incentives for Participation in APMs*, that “to the greatest extent possible, [CMS will] continue to build a portfolio of APMs that collectively allows participation for a broad range of physicians and other practitioners.” CMS further states that “defining PFPM[s] to allow the inclusion of other entities and additional targets gives stakeholders more flexibility in their proposals and may lead to models that promote broader participation in PFPMs, greater potential for care redesign, and greater potential for cost reduction.” We share CMS’s commitment to utilizing providers more effectively to improve beneficiary care and the belief that “finding better ways to deliver care across settings and specialties can lead to improved health outcomes and more efficient health care spending.”

As our organizations have noted in previous comment letters to CMS, pharmacists are very grateful for CMS’s continued recognition of the value of pharmacists and implementation of policies that promote pharmacists’ involvement in patient care, such as pharmacists’ inclusion in payment and care delivery models tested through the CMS Center for Medicare and Medicaid Innovation (“CMMI”);

¹ CMS. Better Care. Smarter Spending. Healthier People: Paying Providers for Value, Not Volume. Fact Sheets. January 26, 2015. Available at:

<https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-01-26-3.html>

² See The Patient-Centered Primary Care Collaborative. “Integrating Comprehensive Medication Management to Optimize patient Outcomes”. June 2012. Available at: <https://www.pccpc.org/guide/patient-health-through-medication-management>

recognition of pharmacists as providers of Medication Therapy Management (“MTM”) services in Medicare Part D; the modified incident to physician supervision requirements for transitional care management (“TCM”) services and chronic care management (“CCM”)³; and inclusion of pharmacist-specific quality and other metrics in the Proposed Rule. In addition, pharmacists appreciate the opportunities for integration into other CMS and CMMI Initiatives, including the Comprehensive Primary Care Initiative (“CPCI”), the Hospital Engagement Networks (“HEN”) and the Transforming Clinical Practice Initiative (“TCPI”)⁴. Better inclusion of pharmacists in Medicare beneficiaries’ care is an important step toward maximizing the benefits of coordinated team-based care—a win for patients and for overall health care quality and cost.⁵

Pharmacists provide valuable medication- and health-related services in many different practice settings, including clinics, physician office practices, community pharmacies, managed care organizations, Federally Qualified Health Centers (“FQHCs”), long-term care facilities, and hospitals and health systems. With nearly 86% of Americans living within five miles of a community pharmacy⁶, the inclusion of pharmacists as part of patients’ health care teams can have a profound impact on access, quality, health outcomes and costs, particularly in medically underserved communities. At a time when medication-related problems generate close to \$300 billion in annual health care costs⁷, the medication expertise pharmacists bring to the patient care team is invaluable—but it is hardly the only service they provide. Pharmacists can provide a broad array of services, including comprehensive medication management, disease management, smoking cessation counseling, health and wellness screenings and services, pain management programs, substance use disorder treatment and care transition services.⁸ However, despite pharmacists’ extensive clinical expertise and training, access to the full complement of pharmacists’ services—for patients and clinical teams—is often constrained by fragmented, inadequate payment structures, which have not kept pace with the evolving health care system and pharmacy profession.

While the Proposed Rule contains numerous provisions referencing the need for and value of team-based care, a pharmacist is not an “eligible clinician” under MACRA.⁹ Moreover, MACRA is not

³ TCM and CCM were added to the primary care service definition used by the Shared Saving Program in June 2015 (80 FR 32746 through 32748). CMS states in the Proposed Rule that these coordination codes would also be appropriate for assigning services in the MIPS.

⁴ See CMS.gov. Comprehensive Primary Care Initiative. Available at: <https://innovation.cms.gov/initiatives/comprehensive-primary-care-initiative/>; Hospital Engagement Networks. Available at: <https://partnershipforpatients.cms.gov/about-the-partnership/hospital-engagement-networks/thehospitalengagementnetworks.html>; TCPI. Available at: <https://innovation.cms.gov/initiatives/Transforming-Clinical-Practices/>. Accessed June 15, 2016.

⁵ See Avalere Health. Exploring Pharmacists’ Role in a Changing Healthcare Environment. May 2014. Available at: <http://avalere.com/expertise/life-sciences/insights/exploring-pharmacists-role-in-a-changing-healthcare-environment>

⁶ NCPDP Pharmacy File, ArcGIS Census Tract File. NACDS Economics Department.

⁷ New England Healthcare Institute. Thinking Outside the Pillbox: A System-Wide Approach to Improving Patient Adherence for Chronic Disease. August 2009. Available at: <http://www.nehi.net/publications/17-thinking-outside-the-pillbox-a-system-wide-approach-to-improving-patient-medication-adherence-for-chronic-disease/view>

⁸ See Avalere Health. Exploring Pharmacists’ Role in a Changing Healthcare Environment. May 2014. Available at: <http://avalere.com/expertise/life-sciences/insights/exploring-pharmacists-role-in-a-changing-healthcare-environment>

⁹ See Section 1848(k)(3)(B) - uses the term “eligible professional.” Both eligible clinician and eligible professional mean any of the following: (i) A physician. (ii) A practitioner described in section 1842(b)(18)(C). (iii) A physical or occupational therapist or a qualified speech-language pathologist. (iv) A qualified audiologist (as defined in section 1861(l)(3)(B)). 1842(b)(18)(C) of the Social Security Act defines a “practitioner” as any of the following: (i) A physician assistant, nurse practitioner, or clinical nurse specialist (as defined in section 1861(aa)(5)). (ii) A certified registered nurse anesthetist (as defined in section 1861(bb)(2)). (iii) A certified nurse-midwife (as defined in section 1861(gg)(2)). (iv) A clinical social worker (as defined in section 1861(hh)(1)). (v) A clinical psychologist (as defined by the Secretary for

the first time that new care payment and delivery models purporting to hinge on the concept of coordinated team-based care have relied on established Medicare fee-for-service (“FFS”) definitions of health care practitioners that leave out many important members of the health care team, including the pharmacist. The Medicare Shared Savings Program (“MSSP”), which was created by the Patient Protection and Affordable Care Act (Public Law 111-14) to facilitate coordination and cooperation among providers to improve the quality of care, uses a similar definition when defining an accountable care organization (“ACO”) professional.¹⁰ Overall, our organizations believe that the creation of opportunities for pharmacists to directly bill Medicare under MIPS and APMs, like other “eligible clinicians,” will facilitate the integration of pharmacists into team-based care models and increase patient access.

As CMS is aware, the number and complexity of medications continues to rise, thereby increasing the importance and impact of services related to medications, such as medication management, in optimizing patient outcomes. A significant number of MIPS quality measures are related to medications, and scores on these measures would benefit from appropriate medication use. Given the potential positive impact of pharmacists’ services on patients and the health care system generally and the fact that no other health care professional has more medication-related experience than pharmacists, our organizations strongly encourage CMS to recognize the benefits of pharmacists and their services in MIPS and APMs. Furthermore, leveraging pharmacists and their medication expertise, will create practice efficiencies and increase patients’ access to health care. Accordingly, our organizations strongly encourage the development of payment and delivery mechanisms and policies that reflect the current health care environment and optimize roles and contributions of all health care providers. We believe policies that promote the effective utilization of health care professionals like the pharmacist in Medicare, including in new payment and delivery models like MIPS and APMs, will have a long lasting impact on patient care and Medicare’s sustainability.

Section 101(c) of MACRA adds a new Section 1848(q)(11) to the Social Security Act, that provides for “technical assistance to MIPS eligible clinicians in small practices, rural areas, and practices located in geographic health professional shortage areas (HPSAs).” While our organizations agree with the goals of this provision, we are concerned that many beneficiaries will not benefit from this provision due to the lack of “eligible clinicians” in their area. As stated previously, a vast majority of Americans live near a pharmacy, but because Medicare provisions do not recognize pharmacists and their services, pharmacists, while available and accessible, are unable to meet the needs of Medicare’s medically underserved. This barrier has not gone unnoticed and legislation increasing access to health care for Medicare beneficiaries in medically underserved communities through pharmacists’ services has received strong support in the U.S. Congress.¹¹ We request that CMS, through its policies and use of regulatory flexibility optimize the skills and expertise of the pharmacist, often an underutilized resource, in achieving its goals of better care for patients, better health for communities, and lower

purposes of section 1861(ii)). (vi) A registered dietitian or nutrition professional. Available at: https://www.ssa.gov/OP_Home/ssact/title18/1848.htm

¹⁰ See § 1899(h) “(1) ACO PROFESSIONAL.—The term ‘ACO professional’ means— (A) a physician (as defined in section 1861(r)(1)); and (B) a practitioner described in section 1842(b)(18)(C)(i).” Available at: <https://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf>

¹¹ See (H.R. 592/S. 314). The Pharmacy and Medically Underserved Areas Enhancement Act. Introduced January 28, 2015. Available at: <https://www.congress.gov/bill/114th-congress/house-bill/592/text?q=%7B%22search%22%3A%5B%22%5C%22hr592%5C%22%22%5D%7D&resultIndex=1> : <https://www.congress.gov/bill/114th-congress/senate-bill/314/text>

costs.¹² For example, we applaud CMS’s plans to consider using its “authority under section 1848(q)(1)(C)(i)(II) [of the Social Security Act] to expand the definition of MIPS eligible clinician to include additional eligible clinicians (as defined in section 1848(k)(3)(B) of the Act) through rulemaking in future years.” As our nation continues to move towards more accountable and outcome-based APM models, our organizations strongly urge CMS’s support in recognizing the value of pharmacist-provided services. We also urge CMS to work with the U.S. Congress on Medicare improvements that require legislative changes,¹³ especially efforts to increase health care access for medically underserved beneficiaries.

II. Recognizing Pharmacists and Other Health Care Providers’ Contributions to Quality and CPIA Performance Measurement (pgs. 28403, 28533, 28576)

Our organizations applaud CMS’s inclusion of two measures that recognize pharmacists and their vital contributions to the patient care team—the Medication Reconciliation Post-Discharge Quality Measure and the Population Management CPIA Measure. These measures, which are ranked high and medium priority respectively, can help physicians achieve their maximum target composite performance scores (“CPS”) under MIPS. In addition to these pharmacy-specific measures, pharmacists can also contribute to approximately 25% of the 290+ measures in the quality category (outcomes, appropriate use, patient safety, efficiency, care coordination, patient experience, etc.) and many of the measures in the CPIA category. However, because pharmacists are not MIPS “eligible clinicians”, the Proposed Rule makes attribution of a pharmacist’s contributions to the care team difficult to quantify, which could potentially impede the incorporation of pharmacists’ into care teams. With the increasing complexity of medications and the role that proper medication management will play under MIPS, APMs, and Advanced APMs, recognizing the unique and essential contributions that pharmacists make on patient care teams is fundamental to achieving successful APMs and will assist CMS to meet its goals of improving quality of care and reducing costs.¹⁴ Accordingly, our organizations agree with CMS’s recent comments to the Pharmacy Quality Alliance (“PQA”) that “pharmacists should be an integral part of the care team to drive high value care.”¹⁵ Therefore, our organizations strongly urge CMS to seek mechanisms to appropriately attribute the role that pharmacist services and pharmacists play in relevant measures under MIPS and APMs in its forthcoming final rule.

III. Including Pharmacist Representation on the PTAC and Adopting Criteria Prioritizing the Inclusion of Other “Health Care Practitioners” (pgs. 28345-28350)

¹² Agency for Healthcare Research and Quality (AHRQ). Aims of the National Quality Strategy. May 2016. Rockville, MD. Available at: <http://www.ahrq.gov/research/findings/nhqrdr/nhqrdr15/aims.html>.

¹³ See (H.R. 592/S. 314). The Pharmacy and Medically Underserved Areas Enhancement Act. Introduced January 28, 2015. Available at: <https://www.congress.gov/bill/114th-congress/house-bill/592/text?q=%7B%22search%22%3A%5B%22%5C%22hr592%5C%22%22%5D%7D&resultIndex=1> : <https://www.congress.gov/bill/114th-congress/senate-bill/314/text>

¹⁴ HHS. National Strategy for Quality Improvement in Health Care. Report to Congress. Agency for Healthcare Research and Quality (AHRQ). March 2011. Available at: <http://www.ahrq.gov/workingforquality/nqs/nqs2011annlrpt.pdf>, Also See Agency for Healthcare Research and Quality (AHRQ). Aims of the National Quality Strategy. May 2016. Rockville, MD. Available at: <http://www.ahrq.gov/research/findings/nhqrdr/nhqrdr15/aims.html>. Also, See Berwick, Donald. Et al. The Triple Aim: Care, Health, And Cost. *Health Affairs*. May 2008. Vol. 27. No. 3759-769. Available at: <http://content.healthaffairs.org/content/27/3/759.full>

¹⁵ Goodrich, Kate. MACRA and Delivery System Reform. Remarks to the Pharmacy Quality Alliance Annual Conference. Center for Clinical Standards & Quality. CMS. Delivered May 18, 2016.

MACRA established the PTAC to review and assess additional PFPM based on proposals submitted by stakeholders. The Proposed Rule proposes criteria for the PTAC to use in reviewing and making recommendations on PFPM. Our organizations appreciate the independent role that PTAC plays under MACRA and agree with CMS's acknowledgement in the Proposed Rule that "there is merit in allowing other practitioners and facilities to be included in proposed PFPMs." Also, as previously mentioned, we are pleased that CMS recognizes that "defining PFPM to allow the inclusion of other entities and additional targets gives stakeholders more flexibility in their proposals and may lead to models that promote broader participation in PFPMs, greater potential for care redesign, and greater potential for cost reduction." Therefore, we look forward to being involved in the PTAC process.

A. Including Pharmacist Representation on the PTAC

Pharmacists provide value to the health care team by improving the delivery of patient care and health outcomes. Our organizations plan to nominate a pharmacist with national recognition and expertise in PFPMs to serve on the PTAC, and we would appreciate CMS's support for pharmacist representation. Pharmacists are integral and accessible members of patient care teams and with more medication-related expertise than any other health care professional, pharmacists will be able to provide a unique perspective when evaluating new PFPMs.

B. Adopting Criteria that Prioritizes the Inclusion of Other "Health Care Practitioners" into PFPMs

Our organizations support CMS's decision to "not propose to limit a PFPM to exclusively targeting physicians and physician services because we believe that stakeholders should be able to propose payment models that include additional types of entities, as well as additional services." Accordingly, our organizations urge CMS to adopt criteria that will lead to inclusion of PFPM proposals that effectively integrate and optimize the roles of other "health care practitioners", including pharmacists.

We offer the following suggestions to the proposed PFPM criteria and have organized them in accordance with the three categories of criteria outlined in the Proposed Rule:

1. *Incentives: Pay for higher-value care*—New PFPM proposals should include pharmacist services that contribute towards paying for value over volume, increase flexibility for physicians to provide even higher quality care, maintain health care quality while decreasing cost, include a payment methodology that acknowledges complete patient care teams, and expand CMS's APM portfolio to include pharmacist models that have met a level of success, such as those currently under CMMI¹⁶ grants, with clearly evaluable goals for quality of care that lower overall health care costs;
2. *Care Delivery Improvements: Promote better care coordination, protect patient safety, and encourage patient engagement*—New PFPM proposals should also include pharmacist services that promote better care coordination; protect patient safety; and encourage patient engagement, greater integration and care coordination among practitioners and across settings, and greater attention to the health of the population served, while also supporting the unique needs and preferences of individual patients; and
3. *Information Enhancements: Improving the availability of information to guide decision-making*—While we agree that PFPM proposals should also encourage the use of HIT to

¹⁶ CMMI has the statutory authority to waive any laws or regulations for purposes of testing a PFPM or other payment model.

inform patient care, we believe that criteria under this category should be modified to explicitly address improving the availability of information to all members of the care team, including pharmacists, to guide decision-making. Such a change is warranted to build a foundation for team-based care and communication, and to prevent inclusion of PFPMs that do not address information sharing. Since the majority of pharmacists do not have access to patients' EHRs, they are often lacking important clinical information in caring for their patients and limited in their ability to communicate effectively and efficiently with physicians and other members on the care team. For example, pharmacists often cannot send or receive continuity of care documents ("CCDs"), pharmacy care notes ("PCNs") or other structured documents between entities. As members of the care team that are most accessible to patients once they leave physicians' offices, pharmacists receive questions related from patients that they could resolve seamlessly if patients' information is made available. In addition, effective and safe delivery of pharmacists' patient care services requires pharmacists to have access to pertinent data like diagnoses, lab values, and patient goals of therapies. Therefore, we suggest CMS modify the criteria to include enhancements that improve pharmacists' access and exchange of information with physicians.

IV. Improving Clinical Information Exchange Between Pharmacists and Other Practitioners (pgs. 28171, 28397)

Pharmacists regularly provide the kind of services envisioned and valued by the concepts within the Proposed Rule, including safe and appropriate medication use; adherence for the elderly and other populations; medication reconciliation; wellness and prevention; chronic disease management programs; and case management for beneficiaries with multiple medications that require complex medication dosing regimens. However, pharmacists are frequently blocked from the bi-directional exchange of relevant clinical information which is critical to maximize the benefit of coordinated team-based care. In an effort to support health information exchange and prevent information blocking, the MACRA law requires that "to be a meaningful EHR user, an EP must demonstrate that he or she has not knowingly and willfully taken action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology".¹⁷ Accordingly, we agree with the Proposed Rule's requirement that a MIPS eligible clinician must attest that the certified EHR technology used was "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.", [including pharmacists] (as defined by 42 U.S.C. 300jj(3))¹⁸, including unaffiliated providers, and with disparate CEHRT and health IT vendors."¹⁹

Additionally, our organizations support the comments submitted by the Pharmacy Health Information Technology ("HIT") Collaborative on the Proposed Rule. Enabling pharmacist access to relevant patient information through interoperable HIT and certified EHRs under Medicare is essential

¹⁷ See Section 1848(o)(2)(A)(ii). Pgs. 380-381. April 11, 2016. Available at:

[http://legcounsel.house.gov/Comps/Social%20Security%20Act-TITLE%20XVIII\(Health%20Insurance%20for%20The%20Aged%20and%20Disabled\).pdf](http://legcounsel.house.gov/Comps/Social%20Security%20Act-TITLE%20XVIII(Health%20Insurance%20for%20The%20Aged%20and%20Disabled).pdf)

¹⁸ 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 1395l(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."

¹⁹ See 81 Fed. Reg. 28172, 28397.

to improve patient care and help practitioners deliver effective care. Implementing the Proposed Rule without addressing pharmacists' need for and reporting of information limits the integration of pharmacists into care teams, fails to utilize pharmacists' expertise and experience and is inconsistent with the principles of value-based and coordinated care models that underpin the Proposed Rule.

Thank you for the opportunity to provide feedback on the Proposed Rule and for your consideration of our comments. We encourage CMS to use our organizations as a resource as it considers new health care payment and delivery mechanisms and look forward to working with CMS on identifying and implementing policy to improve the care provided to Medicare beneficiaries.

Sincerely,



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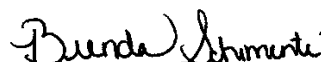
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A handwritten signature in black ink, appearing to read "Ronna B. Hauser". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Ronna Hauser, Pharm.D.
Vice President, Policy & Regulatory Affairs
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