

support for the regulatory changes, especially those concerning use of the term “licensed independent practitioner,” aspects of those aimed at infection control and antibiotic stewardship, and those focused on reducing burden and costs for CAHs in the provision of dietary and nutritional services while increasing the effectiveness and benefits of those vital services for patients. However, some commenters expressed concern that we underestimated the time and effort required for compliance with the antibiotic stewardship and Quality Assessment and Performance Improvement (QAPI) requirements, especially for smaller hospitals, including CAHs. Commenters requested a delayed implementation for these particular requirements.

This document announces an extension of the timeline for publication of the final rule due to exceptional circumstances. We were not able to meet the 3-year timeline for the publication of the final rule due to the complexity and substantive nature of the provisions proposed in the June 16, 2016 proposed rule. Additional time is needed to fully consider all the comments and provisions, and to ensure that we most appropriately modernize and revise the requirements of the CoPs for hospitals and CAHs. Some of these proposed changes include provisions to address—(1) use of the term “Licensed Independent Practitioners;” (2) requirements that do not fully conform to current standards for infection control; (3) requirements for antibiotic stewardship programs to help reduce inappropriate antibiotic use and antimicrobial resistance; (4) the use of quality reporting program data by hospital QAPI programs; (5) a new requirement for CAHs that mirrors the existing QAPI requirements for hospitals; and (6) a new provision that would allow CAHs to grant qualified dietitians and nutrition professionals ordering privileges for dietary services, mirroring an existing provision in the hospital CoPs.

As stated in the Fall 2018 Unified Agenda of Regulatory and Deregulatory Actions (<https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201810&RIN=0938-AS21>), we may finalize the June 16, 2016 proposed rule by merging some of the provisions into other related rulemaking documents. Currently, we are reviewing comments to determine whether to finalize at least one of the provisions from the June 16, 2016 proposed rule regarding patient rights in hospitals. We plan to address the remaining provisions of the June 16,

2016 proposed rule in future rulemaking.

We stress that our decision in this matter to extend the timeline for issuing a final rule should not be viewed as a diminution of the Department’s commitment to timely and effective rulemaking. Our goal remains to publish, as expeditiously as feasible, a final rule that supports improvements in the quality of patient care through adoption of current standards of practice, while also minimizing the burden on providers to the maximum possible extent. At this time, we believe we can best achieve this balance by issuing this continuation document.

Therefore, this document extends the timeline to finalize the provisions in the June 16, 2016 proposed rule for 1 year, until June 16, 2020.

III. Collection of Information

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the OMB under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: May 6, 2019.

Ann C. Agnew,

*Executive Secretary to the Department,
Department of Health and Human Services.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Ch. IV

[CMS-6082-NC]

RIN 0938-ZB54

Request for Information; Reducing Administrative Burden To Put Patients Over Paperwork

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS; Department of the Treasury.

ACTION: Request for information.

SUMMARY: CMS is committed to transforming the health care delivery system—and the Medicare and Medicaid programs—by putting additional focus on patient-centered care, innovation, and outcomes. As part of our continuing Patients over Paperwork initiative, we have actively solicited feedback from the medical community through Requests for

Information (RFIs), listening sessions, and clinical onsite engagements with front-line clinicians and staff to learn how our administrative requirements and processes affect their daily work and ability to innovate in care delivery. This RFI solicits additional public comment on ideas for regulatory, subregulatory, policy, practice, and procedural changes that reduce unnecessary administrative burdens for clinicians, providers, patients and their families. Through these efforts, we aim to increase quality of care, lower costs, improve program integrity, and make the health care system more effective, simple, and accessible.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on August 12, 2019.

ADDRESSES: In commenting, refer to file code CMS-6082-NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-6082-NC, P.O. Box 8016, Baltimore, MD 21244-8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-6082-NC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Morgan Taylor, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at (410) 786-3458.

Mary G. Greene, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at (410) 786-1244.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for

viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments.

I. Background

CMS is committed to transforming the health care delivery system—and the Medicare and Medicaid programs—by putting additional focus on patient-centered care, innovation, and outcomes. Our top priority is putting patients first and empowering them to make the best decisions for themselves and their families. Our continued goal is to eliminate overly burdensome and unnecessary regulations and subregulatory guidance in order to allow clinicians and providers to spend less time on paperwork and more time on their primary mission—improving their patients' health. We are also modernizing or eliminating outdated regulations to remove barriers to innovation. By reducing unnecessary paperwork, we are unleashing the most powerful force in our healthcare system for improving health outcomes: The clinician-patient relationship.

We launched our Patients over Paperwork initiative in 2017 to focus all of CMS on finding opportunities to modernize or eliminate rules and requirements that are outdated, duplicative, or getting in the way of good patient care. Public input has been critical to CMS achieving more flexibilities and efficiencies. As part of the Patients over Paperwork initiative, we actively solicited feedback from the medical community through requests for information (RFI), listening sessions, and clinical onsite engagements with front-line clinicians and staff to learn how our administrative requirements and processes affect their daily work and ability to innovate in care delivery. Through the RFI process alone, we received over 3,000 responses that outlined current burden and recommendations, which resulted in 1,146 distinct burden topics to address. Topics included, but were not limited to: Audits and Claims; Documentation Requirements; Health Information Technology; Interoperability; Provider Participation Requirements; Quality Measures and Reporting; Payment Policy and Coverage Determinations; the Physician Self-Referral Law; and Telehealth.

Over 2,000 clinicians, administrative staff and leaders, and beneficiaries have participated in our listening sessions and onsite engagements and we continue to send teams out into the field to learn more. This fieldwork helped elucidate how our rules affect workflow and decision-making, and potentially impede innovation. As of February 8, 2019, after reviewing and adjudicating all 1,146 burden topics with executive leadership across the agency, we have resolved or are actively addressing over 80 percent of the actionable RFI burden topics through changes to our regulations, subregulatory guidance, operations, or direct education and outreach to providers and beneficiaries. Please see the Appendix for a sample of what we have accomplished so far.

As we continue to work to maintain flexibility and efficiency throughout the Medicare and Medicaid programs, we would like to continue our national conversation about improvements that can be made to the health care delivery system that reduce unnecessary burdens for clinicians, providers, and patients and their families. Through these efforts, we aim to increase quality of care, lower costs, improve program integrity, and make the health care system more effective, simple, and accessible. For these reasons, we are seeking comments on additional opportunities for improvement through this RFI.

II. Solicitation of Public Comments

We invite the public to submit ideas for regulatory, subregulatory, policy, practice, and procedural changes to better accomplish these goals. Specifically, we are soliciting new ideas not conveyed during our first RFI on this matter and innovative ideas that may help broaden perspectives about potential solutions. Ideas may include, but are not limited to:

- Modification or streamlining of reporting requirements, documentation requirements, or processes to monitor compliance to CMS rules and regulations;
- Aligning of Medicare, Medicaid and other payer coding, payment and documentation requirements, and processes;
- Enabling of operational flexibility, feedback mechanisms, and data sharing that would enhance patient care, support the clinician-patient relationship, and facilitate individual preferences; and
- New recommendations regarding when and how CMS issues regulations and policies and how CMS can simplify rules and policies for beneficiaries, clinicians, and providers.

We are particularly interested in recommendations on how CMS could:

- Improve the accessibility and presentation of CMS requirements for quality reporting, coverage, documentation, or prior-authorization;
- Address specific policies or requirements that are overly burdensome, not achievable, or cause unintended consequences in a rural setting;
- Clarify or simplify regulations or operations that pose challenges for beneficiaries dually enrolled in both Medicare and Medicaid and those who care for such beneficiaries; and
- Simplify beneficiary enrollment and eligibility determination across programs.

We are requesting respondents provide complete, clear, and concise comments that include, where practicable, data and specific examples.

III. Collection of Information Requirements

Please note, this is a request for information (RFI) only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

We note that this is a RFI only. This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. This RFI does not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, we are not seeking proposals through this RFI and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. We note that not responding to this RFI does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this RFI

announcement for additional information pertaining to this request. In addition, we note that CMS will not respond to questions about the policy issues raised in this RFI.

We will actively consider all input as we develop future regulatory proposals or future subregulatory policy guidance. We may or may not choose to contact individual responders. Such communications would be for the sole purpose of clarifying statements in the responders' written responses. Contractor support personnel may be used to review responses to this RFI. Responses to this notice are not offers and cannot be accepted by the Government to form a binding contract or issue a grant. Information obtained as a result of this RFI may be used by the Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. In addition, we may publically post the public comments received, or a summary of those public comments.

Dated: April 22, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: June 3, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

Appendix: Patients over Paperwork Sample Accomplishments

The following is a sample of CMS accomplishments reducing unnecessary administrative burden in response to input from clinicians, providers, beneficiaries, and other stakeholders. For more Patients over Paperwork highlights, visit <https://www.cms.gov/About-CMS/story-page/patients-over-paperwork.html>.

Reducing Regulatory Burden

- Removed data elements from the Outcomes and Assessment Information Set (OASIS) assessment instrument.
- Removed the inpatient admission order documentation requirement in an effort to reduce duplicative documentation requirements at the time of admission.
- Removed the requirement that certification/recertification statements detail where in the medical record the required information can be found.
- Established the innovative new classification system, the Patient Driven Payment Model (PDPM), that ties skilled nursing facility payments to patients' conditions and care needs rather than volume of services provided, and simplifies

complicated paperwork requirements for performing patient assessments by significantly reducing reporting burden.

- Eliminated the requirement that certifying physicians estimate how much longer skilled services are required when recertifying the need for continued home health care.
- Proposed giving facilities the flexibility to review their emergency program every 2 years, or more often at their own discretion, in order to best address their individual needs.
- Proposed allowing multi-hospital systems to have unified and integrated Quality Assessment and Performance Improvement (QAPI) and unified infection control programs for all of its member hospitals.
- Published a proposed rule to streamline Medicaid & CHIP managed care regulation.
- Issued Medicare Advantage (MA) and the prescription drug benefit program (Part D) final rule that promotes innovation, empowers patients and providers to make healthcare decisions, and includes burden-reducing provisions.

Simplifying Documentation Requirements

- Changed policy to allow a teaching physician to rely on medical student documentation and verify it rather than re-documenting the evaluation and management (E&M) service, and explained that the physician's signature and date is acceptable verification of the medical student's documentation.
- Provided an exception so that physicians acting as suppliers do not need to write orders to themselves.
- Simplified the requirements for preliminary/verbal Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) orders: Suppliers may dispense most items of DMEPOS based on a verbal order or preliminary written order from the treating physician.
- Clarified DMEPOS written order prior to delivery date requirements: If the written order is dated the day of or prior to delivery, there is no need for affirmative documentation of it being "received".
- Clarified that a supplier can use the discharge date as the date of service if mailing 1 or 2 days before discharge.
- Released a newly revised Skilled Nursing Facility Advanced Beneficiary Notice (SNFABN) with concise instructions and no longer using the 5 denial letters and Notice of Exclusion from Medicare Benefits—SNF.

Focusing on Meaningful Measures

- Our Meaningful Measures initiative is centered on holding providers accountable for patient health outcomes, safe and efficient care, and making sure the measure sets providers are asked to report on are meaningful to patients and clinicians alike.
- Reduced the burden of reporting quality measures in MIPS with a focus on reporting through electronic means and incentivizing the use of clinical registries.

Improving Operational Efficiencies and Interoperability

- In implementing the Quality Payment Program (QPP), established a consolidated data submission experience for the different performance categories of the Merit-based Incentive Payment System (MIPS) so that clinicians no longer need to submit data in multiple systems as under the legacy programs (the Physician Quality Reporting System (PQRS) and the Medicare Electronic Health Record (EHR) Incentive Program).
- Refocused the Medicare EHR Incentive Program (now called the Promoting Interoperability Program) on interoperability, emphasizing exchange of health information between patients and providers.
- Implemented changes resulting in faster processing of state requests to make program or benefit changes to their Medicaid program through the state plan amendment (SPA) and section 1915 waiver review process.

Enhancing Transparency and Consistency

Made significant changes to the Medicare Program Integrity Manual Chapter 13 to improve transparency in the Local Coverage Determination process. The manual includes instructions, policies and procedures for Medicare Administrative Contractors (MAC) that administer the Medicare program in different regions of the country, as well as guidance for stakeholder engagement in the process.

Offering Burden-Reducing Flexibilities in Payment Model Demonstrations

- In the Bundled Payments for Care Improvement Advanced (BPCI Advanced) model, CMS issued the Post-Discharge Home Visit Payment Policy waiver which allows for certain services to be delivered in the eligible model beneficiary's home by auxiliary personnel under the general supervision of a participating practitioner.
- In the Next Generation Accountable Care Organization (Next Gen ACO) model, CMS issued the Telehealth Expansion waiver which allows for eligible model beneficiaries to receive Telehealth services in their home.

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

RIN 0648-BI89

Magnuson-Stevens Act Provisions; Fisheries Off West Coast States; Pacific Coast Groundfish Fishery; Pacific Coast Groundfish Fishery Management Plan; Amendment 28

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.