

JUSTICE IN AGING

FIGHTING SENIOR POVERTY THROUGH LAW

September 11, 2017

Submitted electronically to <https://www.regulations.gov>

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1676-P
P.O. Box 8013
Baltimore, MD 21244-8016

Re: CMS-1676-P Physician Fee Schedule and other Medicare Part B payment policies; Request for Information on Flexibilities and Efficiencies

Justice in Aging appreciates the opportunity to provide a response to the above-referenced proposed Medicare Physician Fee Schedule (PFS) and revisions to other Medicare Part B payment policies, as well as the Request for Information on Flexibilities and Efficiencies in the Medicare Program.

Justice in Aging is an advocacy organization with the mission of improving the lives of low income older adults. We use the power of law to fight senior poverty by securing access to affordable health care, economic security and the courts for older adults with limited resources. We have decades of experience with Medicare and Medicaid, with a focus on the needs of low-income beneficiaries, including those dually eligible for both programs.

Our comments are limited to a few sections of the PFS and payment policies proposal.

Payment Accuracy for Prolonged Preventive Services (HCPCS Codes GYYY1 and GYYY2)—Part II(H)(4)(57)

We support for the new proposed G codes for prolonged preventive services as increasing physician compensation for longer appointments necessary to provide preventative care for individuals with disabilities.

We are pleased that CMS has addressed concerns about previously proposed G codes for preventive services requiring additional time, equipment or expertise that would have resulted in additional cost-sharing for beneficiaries. The G codes in the 2018 proposed rule apply for additional time spent with individuals, and are not limited to specific conditions or needs and would not be accompanied by increased Medicare cost-sharing, as the proposed codes are limited to preventive health care.

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We appreciate CMS' efforts to address health disparities based on disability and hope that this positive step will continue with additional codes that expand access for people with disabilities. We urge CMS to explore its authority to allow for codes for additional time spent with patients outside of preventive services, or, if necessary, to urge Congress to provide such authority.

Evaluation & Management (E/M) Guidelines and Care Management Services – Part II(I)

We support CMS' continued attention to improve the PFS to reflect the value and costs of providing care management services. We strongly urge CMS to ensure that reducing administrative burden is done in a way that promotes the value of these services, especially in reducing disparities among people with greater health needs including those with chronic conditions and disabilities.

We are pleased that CMS is specifically seeking input from patient advocates on reforming the E/M guidelines. Although reducing the specification of detail required for the history and physical exam components may be appropriate, we believe it is important to maintain a requirement that both history and physical exam are documented in some form. As CMS notes, the medical decision making and time are the more significant factors in distinguishing visit levels; however, some documentation of history and physical exam are necessary to support the complexity of the medical-decision making component. Furthermore, we believe that requiring this documentation for payment purposes benefits patients by resulting in more comprehensive medical records and consistency of information across providers.

New Care Coordination Services and Payment for Rural Health Clinics (RHCs) and Federally-Qualified Health Centers (FQHCs)—Part III(A)

We support the proposal to create new G-codes for RHCs and FQHCs to bill for care management services. These services are critically important to RHC and FQHC patient populations who have complex health care needs, and we believe that the providers serving them should be able to bill and be paid for providing these services.

In designing these codes, we appreciate the attention to promoting integrated care management and minimizing reporting burdens on RHCs and FQHCs to encourage provision of care-coordination services. We ask that CMS carefully consider comments received from both providers and patient advocates with respect to the appropriateness of bundling the CCM and general BHI codes and be open to considering alternative approaches should that bundling prove inappropriate. One concern we have is whether this two-code approach accurately reflects and compensates RHCs and FQHCs for the additional complexity of care coordination for their patients who have significant primary care needs. It appears that the newly proposed psychiatric CoCM code would allow for higher compensation for those with higher behavioral health needs, but it is not clear that the equivalent for a patient with higher non-behavioral health needs is accounted for in these two codes.

Medicare Shared Savings Programs—Part III(H)

We are concerned with CMS' intention to change the application narrative and documentation requirements for participating in the Medicare Shared Savings Program with respect to the care processes and patient-centeredness criteria under § 425.112. We appreciate that CMS has considered the value of the narrative in its experience of determining whether an applicant is eligible for the program and understand the desire to eliminate unnecessary documentation. However, we are concerned that replacing the narrative with a certification may result in some program applicants simply checking the box to say that they have these processes which contain critical patient protections without actually considering whether the ACO is prepared to implement them in the context of the Shared Savings Program.

As CMS states, these narratives can be useful to understand the level of an ACO's readiness for participation. We also appreciate CMS's observation that ACOs often change these processes from how they described them in their initial application. The fact that ACOs change these processes to reflect actual participants highlights the importance of the ACO's readiness to participate. We believe that the ACO's capacity to evaluate and create or change its care and patient-centeredness processes to best serve beneficiaries is essential to the Shared Savings Program's success and should be adequately reflected in the application process. Therefore, we encourage CMS to find a middle ground to be able to assess an ACO's readiness without requiring a lengthy, detailed narrative. For example, an ACO applicant could be required to submit any existing processes to promote evidence-based medicine, beneficiary engagement, and coordination of care along with a description of its capacity and strategy for evaluating and updating these processes. This documentation would focus more on the ACO's capacity to meet these requirements rather than on the details of how they will do so.

Finally, regardless of whether the certification process is adopted as proposed or with some additional documentation required, we agree that it is important for CMS to retain the discretion to request that an ACO submit additional information regarding its care processes and patient-centeredness criteria at any time.

Medicare Diabetes Prevention Program (MDPP)—III(K)

We appreciate that CMS is moving forward with an expanded model test that will allow seniors at risk for diabetes to participate in an evidence-based diabetes prevention program.

We support CMS' proposal to require all MDPP suppliers, whether or not they are participating in Medicare, to accept assignment. In particular, we appreciate CMS' recognition that as MDPP services are additional preventive services and therefore not subject to Part B cost-sharing, MDPP suppliers would not be allowed to bill or collect any payment from the beneficiary under

this proposal. The clarity of this policy will help avoid improper billing and promote utilization of this benefit.

We also support CMS' intention to allow beneficiaries who develop type 2 diabetes to continue to receive the MDPP benefit after they have started the program. The education gained in MDPP programs is generally appropriate for individuals with type 2 diabetes, as well as those with cardiovascular disease, and will help them better manage their disease and thereby lower the costs to the Medicare program in the long run. We urge CMS to encourage MDPP suppliers to suggest newly diagnosed type 2 participants talk to their physician about their diabetes diagnosis and the potential benefits of additional Medicare covered services such as diabetes self-management therapy (DSMT).

We are concerned, however, that the once-per-lifetime limit for MDPP included in the proposed rule will punitively deny some beneficiaries the benefits of the program. The majority of private payers who cover and reimburse diabetes prevention programs consider the intervention an annual benefit and the MDPP model test allowed participants to reenroll after the yearlong program if they were still eligible. Furthermore, we note that under the Medicare obesity counseling benefit, doctors are allowed to reassess a beneficiary for additional obesity preventive benefits after a six month period if they failed to achieve the original weight loss goal.¹ Similarly, Medicare coverage policy is aligned with the literature on tobacco cessation and Medicare covers smoking cessation services two times per year for beneficiaries.² Therefore, we strongly urge CMS to rescind the once-per-lifetime limit and, similar to Medicare coverage of obesity counseling and tobacco cessation, provide beneficiaries additional opportunities to participate in and benefit from MDPP.

While we recognize that items or services that are not traditionally covered by Medicare such as gym memberships, fitness trackers, and digital scales may significantly improve beneficiary success in the MDPP, we strongly urge CMS to clarify that MDPP suppliers are prohibited from requiring MDPP participants to shoulder any of the costs of such incentives, including any incentive structures that financially penalize beneficiaries for non-compliance or failure to reach goals. We also urge CMS to carefully evaluate the effects of permitted incentives to inform their future use. Further, we ask that CMS solicit additional input regarding the feasibility of MDPP suppliers bearing the costs of such incentives without cost-shifting to beneficiaries.

¹ Centers for Medicare & Medicaid Services, National coverage determination (NCD) for intensive behavioral therapy for obesity (November 2011), available at www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=353&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&Keyword=obesity&KeywordLookUp=Title&KeywordSearchType=And&bc=gAAAAABAAAAA

² Centers for Medicare & Medicaid Services, National coverage determination (NCD) for smoking and tobacco-use cessation counseling (March 2005), available at www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=308&ncdver=1&DocID=210.4&ncd_id=210.4&ncd_version=1&basket=ncd%25253A210%25252E4%25253A1%25253ASmoking+and+Tobacco%25252DUse+Cessation+Counseling&bc=gAAAAAgAAAAAA%3D%3D&

Request for Information on Flexibilities and Efficiencies

We appreciate CMS's solicitation of feedback on achieving transparency, flexibility, program simplification and innovation and it considers future regulatory action. We share the goal of putting a strong focus on patient-centered care to improve outcomes for Medicare beneficiaries and believe this focus is especially important as CMS works to reduce health disparities. As the administration considers ways to reduce complexity, we encourage CMS to ensure that all policies and procedures are designed to protect patients and consumers. Beneficiaries require robust tools and protections that allow them to access health care that they need.

Modernize and Improve Data Capabilities and Expand Data Sharing

Eligibility and enrollment issues related to the Medicare program are persistent concerns we hear from advocates across the country. The specifics vary but at their core the problems often are not policies but rather the computer systems and protocols upon which implementation depends. When those systems fail, the costs to beneficiaries, states, CMS and the managed care plans and prescription drug plans in which beneficiaries enroll can be significant. Of particular concern is the interface between Social Security systems, CMS systems and State Medicaid systems which affect timely recognition of dual eligibility status, of enrollment in Medicare Savings programs, and of eligibility for the Part D Low Income Subsidy.

We support the efforts by both CMS and the Social Security Administration to improve the quality and frequency of data transfer. For example, CMS has launched data sharing initiatives to offer providers, Medicare Advantage plans and Medicaid programs information on health care status and service usage of Medicare beneficiaries. We believe leveraging this information offers promise to improve and better coordinate care and encourage CMS to prioritize and seek necessary funding to carry out its efforts to improve and innovate health data coordination.

Enhance Beneficiary Choice and Education

We appreciate CMS's focus on ensuring beneficiaries can make the best choices in their healthcare. Choosing the best form of Medicare coverage is a difficult, yet crucial process for beneficiaries. Too many Medicare beneficiaries still do not understand or have access to tools and unbiased assistance for comparing and choosing among available plan options. We encourage CMS to revisit the supports offered to beneficiaries through Medicare Plan Finder, CMS and plan notices, and Star Ratings to help simplify and assist beneficiaries in making choices that best fit their individual health needs.

Specifically, we encourage CMS to update and improve **Medicare Plan Finder** by:

- Allowing for apples-to-apples comparison of all possible plan combinations on one page, including Medicare supplemental policies. Plan Finder does not include Medigap plans and other supplemental coverage together, preventing side-by-side comparison of all

possible plan options and combinations on one page. Beneficiaries may access information about these various options on other pages, but it is difficult to compare them with the Medicare options included on Plan Finder.

- Providing in-depth and more personalized estimated out-of-pocket costs for beneficiaries. For example, the summary results show the range of cost sharing the plan employs, but do not include information about what the cost sharing will be for the beneficiary's prescription drug list until clicking to see more details. Particularly where coinsurances (rather than copayments) are used, seeing dollar amounts for the range of expected costs on the plan comparison page would be useful.
- Including searchable, up-to-date provider networks and integrated comparative information on supplemental insurance benefits. Currently, the tool provides information about pharmacy networks, but only limited information about provider networks. Plan Finder directs users to the plan's website for additional network information; however, plan websites frequently require starting a search from scratch, choosing the correct network that matches the plan, and navigating through multiple webpages instead of linking directly to the provider directory.
- Streamlining the site's layout and overall design to help beneficiaries easily understand and navigate.

We encourage CMS to improve **Beneficiary Notices** by:

- Requiring MA plans and Part D plans to mail the Annual Notice of Change (ANOC) and Evidence of Coverage (EOC) separately.
- Individualizing MA and Part D ANOC by including which specific providers are leaving a plan network, which specific prescription drugs are no longer on the plan formulary, and where utilization management tools will be newly applied. Ideally, these customizations should reflect an individual's actual providers, services, and prescription drugs.

We suggest that CMS solicit input from multiple stakeholders, including beneficiaries, on recommendations to improve the ANOC, EOC, and other standardized materials used during the annual election period. CMS's current commitment to stakeholder input through the comment process for the Welcome to Medicare packet is an example of a potential process for modernizing other Medicare notices.

We also recommend that all Low-Income Subsidy (LIS) enrollees who have premium liability should receive the **Chooser's Notice**. Currently, the Part D Low-Income Subsidy (LIS) Chooser's Notice is only sent to choosers with new or increased premium liability relative to the previous year. We are concerned that approximately 300,000 enrollees have reduced or identical premium liability compared to the previous year, but do not receive the notice – regardless of

the cost. Last year, the group averaged about \$22 a month in premiums, just a little less than the overall average of \$24. For LIS enrollees, \$264 per year can be a significant burden. This small change would ensure that the LIS program works more efficiently, and give LIS enrollees the tools they need to choose the lowest cost plans, and thus decrease the financial burden for all stakeholders involved.

Ensure Transparency and Fairness in the Part D plan Market

Part D plan designs have become increasingly complex, making it more and more difficult for consumers to understand and compare their real costs. Many plans have six drug tiers. An increasing number of tiers charge a percentage co-insurance based on the drug's retail price, rather than a set copay amount. Further, there are pricing tiers for preferred and non-preferred retail pharmacies and for preferred and non-preferred mail order pharmacies. Particularly problematic is the fact that plans are not required to maintain a drug's retail price throughout the year. They can adjust prices based on changed agreements with manufacturers. The result is that prices can rise mid-year, sometimes quite dramatically. Yet consumers affected by a major price hike by one plan have no Special Enrollment Period in which to move to a plan that better fit their needs, no transition protections, and no other recourse. Therefore, we recommend CMS establish a Special Enrollment Period for individuals adversely affected by a significant change in co-insurance responsibility mid-year.

Allow Medicare coverage of Skilled Nursing Facility (SNF) care following a hospital observation stay.

Medicare covers Skilled Nursing Facility (SNF) care under certain circumstances. The beneficiary must have Medicare Part A, must require SNF care, and must have a qualifying hospital stay.³ A qualifying hospital stay is at least three consecutive days in the hospital as an admitted inpatient.

Many beneficiaries now go to the hospital and remain there for several days without ever being admitted as inpatients. Patients under this so-called outpatient "observation" status receive care that is indistinguishable from what they would receive as inpatients. The use of observation stays is increasing as a result of multiple factors, including Medicare payment policy changes and increased reporting, increased scrutiny by both public and private payers of short inpatient stays, efficiency advantages for hospitals of observation stays over inpatient admission, incentives to reduce hospital admissions.

Importantly, however, if patients are administratively classified as outpatient and never admitted, they will not be eligible for Medicare coverage of SNF services even if they spend over three days in the hospital in observation. Although hospitals are now required to provide patients with a Medicare Outpatient Observation Notice (MOON) if they are being kept in

³ 42 CFR 409.30.

observation rather than admitted, the notice is purely informational; the beneficiary cannot challenge the outpatient status or file a legal appeal. This means that if they are transferred to a SNF, they will be responsible for the entire cost of their care.

According to the Congressional Research Service (CRS), in 2012, Medicare beneficiaries had more than 600,000 hospital stays of three days or longer but would not have qualified the beneficiary for SNF services because the patient was classified as an outpatient for some or all of the stay. More than 25,000 beneficiaries were discharged to an SNF following their hospital stays even though they did not qualify for Medicare Part A SNF coverage because the 3-day inpatient stay requirement was not met. They could have been liable for substantial costs received during their SNF stays including bed and board, drugs/biologicals, durable medical equipment, and nursing care.⁴

Furthermore, both the 3-day stay requirement and the observation stay exclusion can usurp the provider's role in determining what care is medically necessary and in the best interest of the patient. Providers must provide safe and adequate care and discharge planning for patients, and hospitals are not permitted to discharge a patient if there is no such safe discharge plan. Therefore, a Medicare beneficiary who needs SNF care but has not had a "qualifying hospital stay" may not be admitted to an SNF as most will not accept a private pay patient who does not have the resources to guarantee payment.

This policy presents a quandary for patients and their providers and leads to more costly care as patients are forced to either unnecessarily extend their hospital stays or self-discharge against medical advice and return home before they are physically or mentally ready. CMS has recognized this significant barrier to accessing SNF care by allowing plans participating in dual-eligible demonstrations, Medicare Advantage plans and certain Accountable Care Organizations participating in the Shared Savings Program to waive the 3-day rule. However, the 3-day rule still applies to many Medicare beneficiaries, restricting their access to Part A SNF coverage.

We urge CMS to eliminate the bureaucratic hurdle Medicare beneficiaries and providers currently must navigate by using its existing authority to categorize observation stays as inpatient for the purpose of Medicare coverage of SNF care.

Streamline Medicare Part D Coverage Determinations and Appeals

The multi-step, prolonged Part D exceptions and appeals process proves onerous and time-consuming for Medicare beneficiaries, pharmacists, and prescribing physicians and can significantly delay access to necessary medications. To begin with, many Part D enrollees are unaware of their right to appeal and do not know how to go about initiating the appeals

⁴ Scott R. Talaga, "Medicare's Skilled Nursing Facility (SNF) Three-Day Inpatient Stay Requirement: In Brief," Congressional Research Service (June 2, 2016), available at <https://www.ahcancal.org/advocacy/solutions/Documents/Congressional%20Research%20Services%20Report%20on%20Three-Day%20Stay%20Requirement.pdf>.

process.⁵ Furthermore, Part D enrollees are not provided individualized information or adequate education when refused a medication at the pharmacy counter, resulting in the individual and their physician spending hours trying to obtain this information in order to make a proper exceptions request.

Additionally, rather than being able to appeal the denial at the pharmacy counter, a beneficiary must formally make an exception request, which requires significant time and effort for both the patient and their physician. Only upon receipt of a written denial in response to this request, known as the coverage determination, is the beneficiary permitted to request a formal appeal, termed a redetermination.

Additional administrative efficiency could be gained by aligning the Part D exceptions process with the exceptions and appeals processes in Medicare Advantage (MA), Original Medicare, and Medicaid. In these each of these programs, a beneficiary automatically receives a notice of non-coverage after a service is received or prior to the service because it is not authorized explaining the reason why.

We recommend CMS:

- Require a coverage determination to be provided automatically to a beneficiary at a point-of-sale refusal. Allowing the pharmacy counter refusal to serve as the coverage determination serves the dual purpose of removing a burdensome step for beneficiaries and their doctors while also expediting the appeals process for those who need it;
- In the alternative, require that the existing pharmacy counter notice explain the reason (i.e., prior authorization, step therapy, quantity limits, off-formulary, non-covered, etc.) that the beneficiary is being turned away at the pharmacy counter. This simple, straightforward information would better equip people with Medicare and their providers to navigate the appropriate next steps, whether by requesting a coverage determination or pursuing an alternative medication.
- Require MA plan sponsors to educate providers and pharmacies about the tiering exceptions process and to provide updated lists of drugs the plan considers to be alternatives so that providers can more efficiently assist their patients in obtaining appropriate medications.
- Extend the cost-sharing exception and appeal process to drugs on the specialty tier. The issue remains exceptionally important for beneficiaries with conditions that have limited treatment options (i.e., when all of the therapeutic options fall under the specialty tier and its equivalent higher cost-share for beneficiaries).

⁵ Presentation by Sokolovsky, L., Suzuki, S. and L. Metayer, "Part D exceptions and appeals" (September 2013), available at: http://www.medpac.gov/transcripts/part_d_exceptions_&_appeals.pdf; CMS, "Fact Sheets: Part D Reconsideration Appeals Data, Part D Fact Sheets CY 2011" (2011), available at: <http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Reconsiderations.html>

Promote Better Coordination of DME Coverage Rules for Dually Eligible Beneficiaries

We observe that the misalignment of payment procedures in Medicare and Medicaid results in denials, delays, and higher than appropriate health care costs for essential Durable Medical Equipment (DME) among dually eligible beneficiaries. The logistical problems created by the misalignment of Medicare and Medicaid processing rules create unnecessary administrative complexity and barriers in accessing needed DME among vulnerable older adults and people with disabilities that individuals solely on either Medicaid or Medicare do not experience.

Often, problems arise because suppliers are concerned they will not receive payment from either Medicare or Medicaid given the differences in how the two programs process coverage requests and determine whether to pay for DME. Because Medicaid is the payer of last resort, dual eligible individuals often must wade through the intricate process of provider submissions, Medicare rejection, and eventual Medicaid processing and delivery before receiving a needed item. These steps also inject additional, unnecessary administrative costs and provider time into the approval process.

We encourage CMS to take any steps it can to better align the payment procedures and reduce burden on beneficiaries, their providers, and those administering the approval process. For example, CMS could require state Medicaid programs to review DME requests for DME that Medicare never authorizes without having a Medicare denial.

Ensure Medicare is Covering all Medically Necessary Oral Health Care

The Medicare statute excludes coverage of routine oral health care, which is defined as those services individuals receive when they are not sick. As emphasized in the Senate Report accompanying the enacting Medicare legislation, the exclusion of routine oral health coverage is not an absolute bar to coverage. Instead, Medicare is intended to cover oral health services and procedures in “medically necessary” situations. Examples of specific diseases and procedures for which oral / dental health is necessary, and for which medical clearance is frequently required, include: endocarditis, valvular heart disease, heart valve prostheses, persistent uncontrolled diabetes, solid organ and stem cell transplantation, cancers, cellulitis and sepsis, total arthroplasty, placement of vascular stents and grafts.

Currently, the authorization and reimbursement for procedures for which oral/dental health is medically necessary is more limited than the statute intended. CMS has allowed payment for dental procedures that are incident and integral to a primary covered non-dental procedure. However, CMS has required that both procedures be performed at the same time and by the same dentist. MBPM Pub. 100-02, Ch. 15 § 150. As a result, dental coverage is only granted in extremely limited circumstances, usually in conjunction with jaw surgery. Rather than taking into account clinical standards and protocols and whether a dental procedure is, from a medical perspective, integral to a covered procedure or course of treatment, the “same time/same

dentist rule” arbitrarily hinges coverage on the timing of a dental procedure and who administers it.

Therefore, in order to ensure Medicare is covering medically necessary health care, including oral health care, we recommend CMS:

- Issue policy clarifying that medically necessary oral health care, including essential, non-routine dental procedures, is covered by Medicare.
- Revise its “same time/same dentist rule” to permit payment for dental services and oral health care that are, by accepted standards of medical care, incident and integral to a covered treatment or procedure.

Thank you for the opportunity to submit comments. If any questions arise concerning this submission, please contact me at jgoldberg@justiceinaging.org.

Sincerely,



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