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The Honorable Thomas Price
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018

Dear Secretary Price:

On behalf of MCG, we appreciate the opportunity to provide comments on the proposed Medicare Part B Physician Fee Schedule for CY 2018. Our comments focus specifically on the provisions related to the use of Appropriate Use Criteria (AUC) for advanced imaging.

About MCG

MCG was original founded in 1990 as a wholly-owned subsidiary of Milliman – one of the world's largest actuarial consulting firms. Within Milliman's environment of actuarial science (statistical calculations of risk), a group of physicians and actuaries assembled the latest evidence-based medical research with best practices of care and clinical guidance to create the Milliman Care Guidelines. Once providers saw the depth of MCG content, they recognized the inherent value and began using it inside their own institutions to guide care.

MCG, which is now part of the Hearst Health network, remains a leading provider of independent, clinical care guidelines. MCG helps healthcare organizations implement informed care strategies that proactively and efficiently move patients toward health. MCG's transparent assessment of the latest research and scholarly articles, along with independent data analysis, gives patients, providers, and payers the vetted information they need to feel confident in their care management decisions.

Our care guidelines are used by more than 2,300 health care organizations to help drive effective care for more than 170 million Americans. Our customers include 1,600 hospitals, eight of the ten largest commercial health plans, Medicare Advantage plans, Medicare fee-for-service contractors, state Medicaid agencies, TRICARE contractors, and many others. MCG's clinical editors analyze and classify peer-reviewed papers and research studies each year to develop the care guidelines in strict accordance with the principles of evidence-based medicine. Annually, more than 140,000 references are reviewed and ranked, with over 39,000

unique citations. The guidelines are developed by clinicians who specialize in evidence-based medicine and are thoroughly vetted by clinicians who are actively practicing and seeing patients.

Medicare AUC Initiative

The Protecting Access to Medicare Act of 2014, P.L. 113-93 (PAMA) directed the Centers for Medicare and Medicaid Services (CMS) to establish a program requiring Medicare providers to consult AUC before ordering advanced diagnostic imaging services. We strongly support the goals of this AUC initiative as stated by CMS: "to promote the evidence-based use of advanced diagnostic imaging to improve quality of care and reduce inappropriate imaging services" (Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016, 80 Fed. Reg. 71102). Increasing use of evidence-based care guidelines is critical to reducing unnecessary variation in care and ensuring Medicare beneficiaries receive the most appropriate treatment. We know from experience that effective care leads to the best patient outcomes with the most efficient use of care resources, and we applaud Medicare for moving in this direction. However, we remain concerned that CMS' implementation of this program is inconsistent with the plain language of PAMA and clear congressional intent. **For this reason, MCG supports CMS' proposal to delay the implementation of the Medicare AUC initiative until at least January 2019**, which gives CMS ample time to fix fundamental flaws that will limit the effectiveness of the initiative, particularly related to the issues outlined below.

(1) CMS is inappropriately excluding independent guideline authors with content developed by clinicians and endorsed by provider-led entities.

Although the Medicare AUC program has yet to take effect, CMS has announced two rounds of entities eligible to develop AUC content, the first, a group of 10 guideline content providers, was announced in June 2016 and the second, a group of 7 guideline content providers, was announced in June 2017. Additional guideline content providers may apply to participate on an annual basis. Unfortunately, CMS's interpretation of Congress' directive inappropriately narrows the entities eligible to develop AUC content under the PAMA program by excluding independent guideline authors, including those like MCG with content that is developed by clinicians and endorsed by provider-led entities. It makes no sense to exclude independent guideline authors, which are widely used as the gold-standard in the private sector, and it contradicts the clear language in PAMA. Under PAMA appropriate use criteria is defined as:

> *"criteria only developed **or endorsed by** national professional medical specialty societies or other provider-led entities, to assist ordering professionals and furnishing professionals in making the most appropriate treatment decision for a specific clinical condition for an individual. To the extent feasible, such criteria shall be evidence-based."*

Thus, per the statute, eligible AUC authors could include: (1) national professional medical specialty societies; (2) provider-led entities; **or (3) any other entity with AUC content that is endorsed by a national professional medical specialty society or another provider-led entity.**

While MCG should qualify as a provider-led entity, CMS rejected the application MCG submitted in each of the last two cycles. According to CMS, a provider-led entity must be comprised primarily of providers or practitioners, who, either within the organization or outside of the organization, spend a majority of their time providing direct patient care. To be clear, this is a CMS definition – Congress did not define the term "provider-led entity" in PAMA. What CMS missed in defining this term is the reality that clinicians who spend most of their time seeing patients do not have the capacity to develop and regularly update comprehensive clinical care guidelines. Creating AUC is not a part-time job. Indeed, one of the reasons hospitals and health systems use guidelines is to provide a synthesis of the latest scientific information to clinicians who do not have time to read and independently evaluate every peer-reviewed journal article and study. For context, MCG annually reviews more than 140,000 references with over 39,000 unique citations. Clinicians who spend most of their time seeing patients cannot be expected to do this work. Yet, CMS's implementation of the Medicare AUC initiative prioritizes content developed by clinicians who see patients over clinicians who specialize in reviewing the science and developing guidelines.

While we would encourage CMS to revisit its definition of provider-led entity, there are other ways to ensure independent guideline authors are eligible to participate going forward. As noted above, PAMA explicitly allows AUC content to be considered if it is endorsed by a provider-led entity. **Yet, contrary to the statutory language, CMS unilaterally limited the "endorsement pathway" to a provider-led entity endorsing the content of another provider-led entity.** According to the CMS implementing rule (80 FR 71381):

> *"A qualified PLE may develop AUC, modify AUC developed by another qualified PLE, or endorse AUC developed by other qualified PLEs."*

Thus, under CMS's definition, you have to be a provider-led entity to have your content endorsed by another provider-led entity. This clearly contradicts the statutory language as well as the congressional intent. The endorsement pathway was meant to allow content providers other than national medical specialty societies and provider-led entities to participate, provided that the content was endorsed by a national medical specialty society or provider-led entity. Consistent with the statute, MCG's content is endorsed and used by numerous provider-led entities, however, CMS concluded that MCG and other leading independent guideline authors are ineligible to participate in the AUC initiative because they do not meet CMS's regulatory definition of a provider-led entity.

As CMS finalizes the Part B physician fee schedule for CY 2018, CMS should modify the regulations to allow provider-led entities to endorse any AUC content, including content developed by an author that is not a provider-led entity. Set out below is a marked-up version of the CY 2016 Medicare AUC implementing regulation at 42 C.F.R. §414.94 with suggested modifications (new language in red text):

Under (b) Definitions:

Independent guideline author means (1) an entity that works directly with clinicians, either within the organization or outside the organization to develop AUC content, (2) the AUC content is based on the scientific evidence, and (3) the entity has no financial stake in the outcome of the AUC review.

Specified applicable appropriate use criteria means any individual appropriate use criterion or AUC set developed, modified, or endorsed by a qualified PLE ***or qualified entity.***

Under (c) Qualified Provider Entity:

(c) Qualified provider-led entity.
To be qualified by CMS, a PLE must adhere to the evidence-based processes described in paragraph (c)(1) of this section when developing or modifying AUC. A qualified PLE may develop AUC, modify AUC developed by another qualified PLE, or endorse AUC developed by other ~~qualified PLEs~~. ***qualified entities, including independent guideline authors.***

(-) Qualified entity.
A qualified entity is an independent guideline author with AUC content that is endorsed, pursuant to the processes outlined in (d), by at least one PLE as defined in (b).

(1) Requirements for qualified ~~PLEs~~ ***entities and PLEs*** *developing or modifying AUC. A* ***qualified entity or*** *PLE must perform all of the following when developing or modifying AUC:*

Under (d) Endorsement:

(d) Endorsement. ~~Qualified PLEs~~ ***A PLE as defined in (b)*** *may endorse the AUC set or individual criteria of other qualified PLEs* ***or qualified entities*** *~~under agreement by the respective parties~~;* ***provided that the qualified entity shall remain solely responsible for compliance with the requirements of the AUC program. To qualify for endorsement, a qualified entity shall submit with its application to CMS (a) a list of PLEs currently licensing the AUC content; or (b) a letter of endorsement from at least one PLE currently licensing or intending to license the AUC content.***
~~., in order to enhance an AUC set~~

While there may be other approaches, MCG encourages CMS to realign the Medicare AUC initiative with the statutory language in PAMA to ensure that any entity with AUC content endorsed by a provider-led entity is eligible to participate, provided that the entity also meets the other requirements of the program. MCG would welcome the opportunity to work with CMS on

the development of feasible alternative approaches to the implementation of the Medicare AUC initiative, including for example, the creation of a workgroup to address this issue.

(2) CMS should not require an AUC provider to forfeit intellectual property protection in order to participate in the Medicare AUC initiative.

PAMA requires AUC content be "based on studies that are published and reviewable by stakeholders." While it makes sense to ensure AUC content is based on publicly available research, and guideline content is transparent for providers, patients, and caregivers, CMS's regulations again place barriers to the participation of independent developers of clinical guidelines by requiring that AUC developers put their intellectual property in the public domain.

Specifically, CMS requires that AUC providers place their full guideline content in the public domain. If the guidelines are made available to the public for free, however, the authors will have less incentive to invest the substantial resources required to keep the guidelines updated on a regular basis. Given the rapid pace of medical advancements, patient care will suffer if the guidelines are not kept current. In addition, simply publishing guideline content on a public website is not meaningful transparency, particularly for Medicare beneficiaries and their caregivers. Rather than pointing a Medicare beneficiary to a website with considerable guideline content, most of which is unrelated to their care, CMS should follow the lead of a number of states and ensure Medicare beneficiaries have access, upon request, to relevant AUC criteria, including key citations related to a particular imaging study or studies that are relevant to their care.

During our conversations with CMS, the staff outlined three reasons for this requirement: (1) providing clinicians full access to content; (2) providing beneficiaries with access to any guidelines used in their care decisions; and (3) enabling academic researchers to compare the differences between the various sets of AUC that CMS would approve for use. All of these goals can be met without forcing AUC content providers to publish their content on a public website. Providers would always have full access to AUC – from the guideline content to the referenced studies and peer-reviewed literature. Beneficiaries should have access to the relevant portion of guidelines related to their care, and academic researchers can be granted limited access under an appropriate nondisclosure agreement.

Guideline providers should have flexibility to determine how to ensure their content is transparent. Set out below is a marked-up version of the CY 2016 Medicare AUC implementing regulation at 42 C.F.R. §414.94(c)(1) with suggested modifications (new language in red text):

> Delete existing subparagraphs (iv) and (v):
>
> ~~(iv) Publish each individual criterion on the PLE's Web site and include an identifying title, authors (at a minimum, all members of the multidisciplinary AUC development team must be listed as authors), and key references used to establish the evidence.~~

~~(v) Identify each appropriate use criterion or AUC subset that are relevant to a priority clinical area with a statement on the PLE's or independent guideline author's Web site. To be identified as being relevant to a priority clinical area, the criterion or AUC subset must reasonably address the entire clinical scope of the corresponding priority clinical area.~~

Replace existing subparagraphs (iv) and (v) with the following:

(iv) Ensure AUC criteria, including key citations, is made available to any Medicare provider to review, upon request, and to all Medicare providers who chose to use the AUC criteria and any related CDSM.

(v) Ensure Medicare beneficiaries have access, upon request, to relevant AUC criteria, including key citations, related to a particular imaging study or studies that are relevant to their care.

(vi) Provide CMS a summary regarding annual changes to the AUC criteria.

Conclusion

MCG applauds CMS for proposing to delay the implementation of the Medicare AUC initiative until at least January 2019, which will give CMS ample time to fix the flaws outlined above and ensure the AUC initiative is consistent with PAMA and congressional intent.

Thank you again for the opportunity to provide comments. We would welcome the opportunity to work with you and your team to get the Medicare AUC initiative back on track and ensure Medicare beneficiaries receive the most effective care, consistent with the latest scientific evidence.

Sincerely,

Jonathan L. Shreve

Jon Shreve
President and CEO