September 6, 2016

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1631-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016, Submitted Electronically via www.regulations.gov

Dear Centers for Medicare & Medicaid Services,

As the Executive Directors of the Harvard Medical School Library of Evidence, we humbly submit our remarks regarding the July 15, 2016 "Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016," published by the Centers for Medicare & Medicaid Services (CMS) (the "Proposed Rules"). We specifically focus on §414.94 titled "Appropriate use criteria for advanced diagnostic imaging services" promulgated under Section 218(b) of the Protecting Access to Medicare Act of 2014 (PAMA), a provision that amended Title XVIII of the Act to add section 1834(q), which directed CMS to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services.

About the Harvard Medical School Library of Evidence

The Library is a project of the Harvard Medical School (HMS) Countway Library of Medicine and representatives of HMS hospitals and Harvard institutions. Its goal is to create a sustainable, public repository of medical evidence to enable and promote the broad and consistent practice of evidence-based medicine in the United States in order to improve the quality of care while simultaneously reducing waste and cost.

The Library has been organized to serve as a public resource for medical evidence from all sources and, therefore, focuses on the accumulation, curation, organization and functionalization of medical evidence rather than on the creation of new evidence. It has been developed under the guidance of its Governing Council and Executive Directors to provide an unbiased resource for the grading of evidence, using both the well-validated Oxford Centre for Evidence-based Medicine Levels of Evidence and the U.S. Preventive Services Task Force I-Scores. The Library can be accessed through our webpage at http://libraryofevidence.med.harvard.edu/. As you know, the HMS Library of Evidence is not, itself, applying to become a qualified provider-led entity (QPLE). Instead, it is our hope that national professional medical societies and QPLEs that elect to publish AUC under the program described in the proposed rules will use the Library as a free resource to assist their efforts to comply with the statutory and regulatory requirements. Similarly we

hope that the Library becomes a resource to providers as they evaluate Appropriate Use Criteria (AUC) for local adoption under PAMA. Most importantly, we envision the Library as an ever-expanding source of curated and up-to-date evidence to guide AUC as regulations move beyond imaging to other medical tests and procedures. The clinicians, librarians, and other experts who make up the Library team all have significant expertise in the content areas covered by the Proposed Rules, and our remarks are based on this collective experience.

Our Remarks

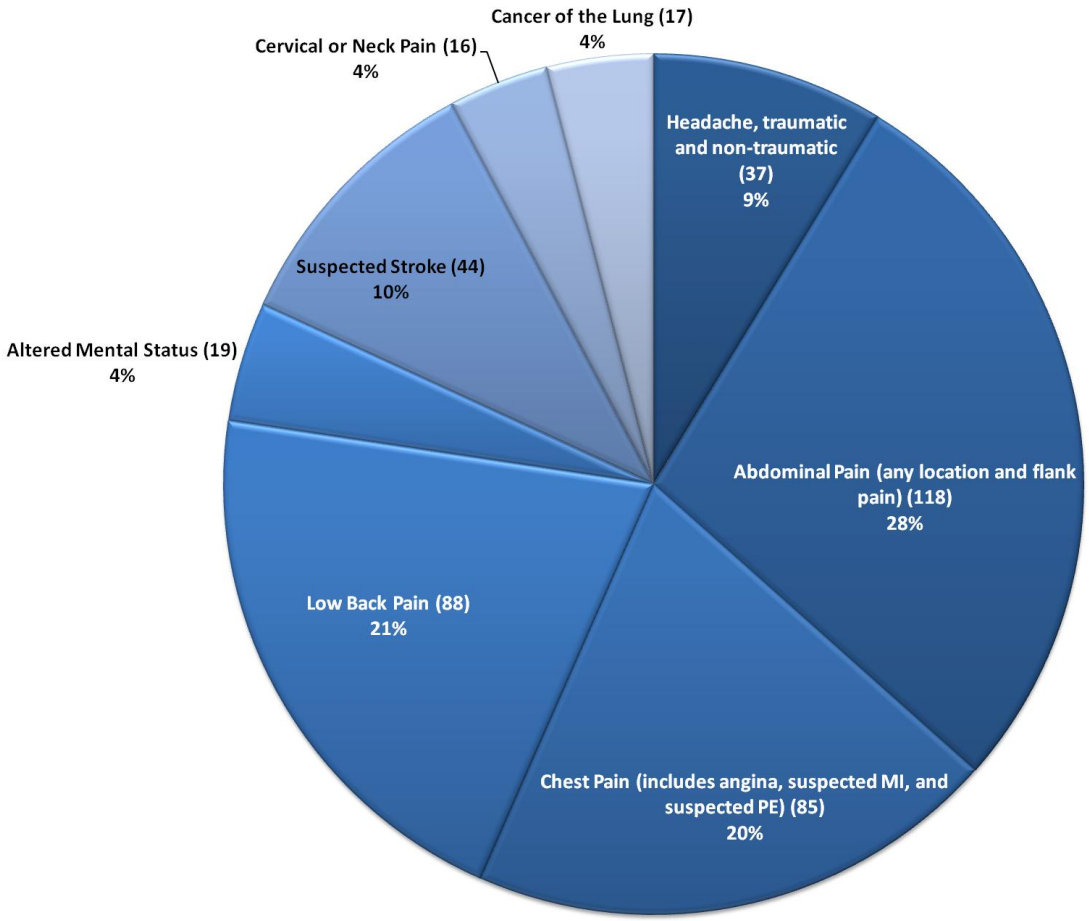
Overall, we would like to congratulate CMS on articulating the vision behind effective implementation of AUC and Clinical Decision Support (CDS) so well in the Proposed Rules. Given our experience with the grading and evaluation of medical evidence, we especially applaud the Proposed Rules' emphasis that "*the goal of this statutory AUC program is to promote the evidence-based use of advanced diagnostic imaging to improve quality of care and reduce inappropriate imaging."* In addition, we thank CMS and Intermountain Healthcare for organizing the multidisciplinary forum we attended, which allowed allowing for active engagement by the diverse stakeholders affected by this program – it was immensely valuable.

As the only curated freely-available library of evidence, our comments will focus on the aspects of the Proposed Rules that pertain to the Priority Clinical Areas. However, it is important to note that we strongly support CMS' intent to support both focused and broad implementations of CDS. In our experience scoring evidence meant to guide imaging across multiple clinical indications, we have found its strength to be highly variable. While QPLEs should be allowed to implement CDS broadly if they so desire, more focused implementations utilizing specific high-quality evidence will be more effective based, on our experience.

Clinical Scope of Priority Clinical Areas

We applaud the Proposed Rule's intention of bridging the aforementioned gap between broad and focused implementations of CDS. However, we are concerned about the statement requiring that Clinical Decision Support Mechanisms (CDSM) include AUC that "reasonably address the entire clinical scope of priority clinical areas" as a floor in order to qualify. While we support the concept of a floor upon which subsequent expansion can be built (and envision a similar expansion for the Library concurrent with that process), we are concerned because – at least for some of the PCAs proposed – covering the "entire clinical scope" with high quality evidence is simply impossible. We will discuss this in detail below, but the chart below may be helpful for overall context. Currently, the Library of Evidence contains over 700 pieces of evidence, 424 of which relate to the PCAs listed in the Proposed Rule.

HMS LoE Evidence Related to CMS PCAs



However, the strength of the evidence for each of these PCAs varies widely. We generally classify evidence graded using the Oxford Centre for Evidence-Based Medicine, Levels of Evidence (2009) as high quality if it is a Level 1-4 – in contrast to Level 5 evidence, defined as "Expert opinion without explicit critical appraisal." For the PCAs listed in the Proposed Rule, the proportion of Level 5 low quality evidence ranges from 8% (for Low Back Pain) to 82% (for Cancer of the Lung.) Attempting to implement AUC coverage for each PCA that addresses the "entire clinical scope" would necessarily require CDSM to include this low quality evidence, which is (we believe) antithetical to CMS' intent.

Instead, we suggest that CMS delegate to QPLEs the authority to rigorously evaluate evidence and formulate AUCs based on this evaluation. If the QPLE determines that high quality evidence exists to inform the development of AUCs related to specific PCAs, then it should be required to implement them. Conversely, if a QPLE determines that there is not

sufficient high quality evidence to support AUC targeting a specific PCA, it should be required to note this publicly, stating which evidence was evaluated and deemed to be of insufficient strength. Given that the HMS Library of Evidence has already conducted these evidence reviews and allows for free public access to our database, we would also support QPLEs referencing our review to meet these requirements.

Specific Priority Clinical Areas

As a multidisciplinary and interprofessional group we agree with the broad concepts behind the PCAs outlined by the proposed rules. These conditions are seen in all patient populations and in healthcare systems both large and small. Most of them have clear opportunities for improved care for CMS beneficiaries through evidence-based recommendations. We do, however, suggest five modifications to the list, for the reasons noted below:

A. Given the clinical significance, varied clinical presentations (often other than chest pain), and prevalence of pulmonary embolism, we support extracting this condition from the Chest Pain category. We suggest creating a separate PCA to govern the imaging of patients suspected of having pulmonary embolism. There is a wealth of validated evidence-based literature surrounding the appropriate imaging for patients with suspected pulmonary embolism, and we believe that this supports its separate and distinct emphasis in the list of PCAs.

B. For the PCA of Abdominal Pain, we suggest the notation of the specific qualifying diagnoses of pancreatitis, appendicitis, and renal colic. While the number of potential causes for abdominal pain is broad, these three diagnoses have strong evidence-bases for imaging. Conversely, there is little high-quality evidence for the imaging of generalized and undifferentiated abdominal pain.

C. For the Cancer of the Lung PCA, we advocate the addition of lung cancer screening to the already present qualifiers of primary or metastatic, suspected or diagnosed. The inclusion of lung cancer screening would be beneficial as there are well defined and evidenced based criteria outlining the population that benefits from screening examinations.

D. We suggest wholly removing Altered Mental Status from the list of PCAs. The wide spectrum of potential clinical causes for Altered Mental Status – including but not limited to toxic, hypoxemic, oncologic, metabolic, environmental, infectious, cardiovascular, neurologic, and psychiatric – make this PCA exceptionally broad without clear evidence-based recommendations for imaging for many of the potential causes.

E. We would support adding the "traumatic" modifier to Cervical or Neck Pain, similar to its inclusion as a modifier for the Headache symptom. There are a number of evidence-based guidelines for imaging of patients with traumatic cervical pain, but a distinct lack of evidence guiding the use of imaging in atraumatic pain.

The Revisions to the Proposed Rule present a true step forward and provide appropriate clarifications for PAMA. We are truly appreciative of the efforts by CMS to implement PAMA in a thoughtful manner and to solicit input regarding this implementation. If we can be of any additional assistance, please contact either of us.

Very Respectfully,

David Osterbur, PhD, MLS
Executive Director
Harvard Medical School Library of Evidence
Interim Director
Francis A. Countway Library of Medicine
Harvard Medical School

Ali S. Raja, MD, MBA, MPH
Executive Director
Harvard Medical School Library of Evidence
Vice Chairman
Department of Emergency Medicine
Massachusetts General Hospital

Submitted Electronically via www.regulations.gov
Submitted via email to: ImagingAUC@cms.hhs.gov
With copies via email to: Sarah.Fulton@cms.hhs.gov
JoAnna.Baldwin@cms.hhs.gov
Joseph.Chin@cms.hhs.gov
Tamara.SyrekJensen@cms.hhs.gov
Joseph.Hutter@cms.hhs.gov