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September 2, 2014

Ms. Marilyn B. Tavenner
Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-1612-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule; Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B Proposed Rule for CY 2015

Dear Ms. Tavenner:

The American Association for the Study of Liver Diseases (AASLD) appreciates the opportunity to comment on the CY 2015 Physician Fee Schedule proposed rule. AASLD is the leading organization of scientists and healthcare professionals committed to the prevention of liver disease, early diagnosis and care of liver disease, and advancing research for cures for liver disease. AASLD was founded in 1950 by a small group of leading liver specialists (hepatologists) to bring together those who had contributed to the field of hepatology. We have grown to an international society responsible for all aspects of hepatology, and our annual meeting, [The Liver Meeting®](#), now has over 10,000 attendees, including physicians, surgeons, researchers, and allied health professionals from around the world. It is considered the premier liver meeting internationally.

The Association looks forward to working closely with CMS as this proposed rule moves toward implementation and offers the following comments which focus on areas of particular importance to our members:

1. Quality Reporting Programs
2. Physician Quality Reporting System (PQRS)

3. Value-Based Modifier
4. Open Payments Program (Sunshine Act)

Quality Reporting Programs

While AASLD is aware that CMS must implement the Physician Quality Reporting System (PQRS), Value-Based Payment Modifier (VM) and Meaningful Use in accordance with existing statute, we are deeply concerned about the penalties that physicians could face if they report incorrectly. If a physician were to fail to satisfy the requirements for all these programs, a 9 percent penalty will be applied two calendar years after the close of the reporting period. This is a serious cause for concern because of the amount of the penalty and the time lapse between reporting and the penalty's application.

While we understand that the Agency is taking steps to harmonize these quality reporting programs and provide more frequent feedback, we cannot stress enough how critical it is that physicians receive as close to real time feedback as possible to have sufficient time to course correct and successfully report during the reporting period. The Association urges CMS to provide participating providers with one comprehensive feedback report on a quarterly basis. This would accomplish both providing more regular feedback, but also allowing those participating to have a more complete picture of where they are succeeding and areas in which they may be subject to penalties.

As the penalties associated with these programs grow, we also remain concerned about risk adjustment. We understand that the VM cost measure includes a formula for risk adjustment, but we remain concerned that this methodology and any that may be applied these quality programs is consistently evaluated and refined. Many hepatologists treat chronically ill patients, including those with fatty liver disease, viral hepatitis and hepatocellular carcinoma. In this population, outcomes are largely influenced by patient compliance. We remind CMS that risk adjustment must account for geographic location and socioeconomic status as well as patient population. Comparisons should consider variations within specialties to ensure performance is measured appropriately.

Physician Quality Reporting System

As CMS attempts to move this program away from claims-based reporting to rely on other reporting mechanisms, like registries and electronic health records (EHRs), we recommend that the agency phase out claims-based measures more slowly. While the claims-based reporting is difficult, the majority of eligible professionals participate in the PQRS by this method. Considering the additional costs associated with reporting via a registry or EHR, AASLD believes it is unfair for CMS to require practices to invest in these reporting methods in this economic climate.

CMS is proposing to remove 73 measures from the program, a number that the agency notes is higher than in past years. Because of the concerns outlined above, we urge CMS to reduce the number of claims-based reporting measures being removed, many of which the AASLD's members use. This is of particular concern to the Association because many of our members still lack appropriate measures based on their area of sub-specialty.

Value-Based Payment Modifier

CMS is proposing to complete the phased-in implementation of the VM in 2015 by applying the program to all physicians. We commend CMS for taking a similar approach as in past years by not putting solo practitioners and groups of 2-10 at risk for a negative adjustment. Given the complexity of the program, we agree with CMS that those new participants should receive the same grace period as those in larger groups received and not face a 4 percent penalty.

However, we are very concerned about the proposed increase in the VM penalty from a maximum of 2 to 4 percent. This 4 percent penalty taken in aggregate with the penalties for the other quality reporting program would likely have a significant impact on all practices, especially the smaller practices. We believe that the CMS should further analyze the data from the program's implementation to date to ensure the program is properly designed and implemented before increasing the amount of payment at risk.

Open Payments Program (Sunshine Act)

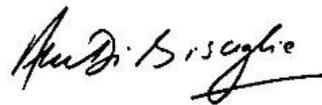
CMS is proposing to revoke the Sunshine Act reporting exclusion for continuing medical education (CME) activities. The proposal would exempt third party transfers for CME only in circumstances where the industry donor is unaware of the recipients before and after the funds are transferred. We believe that this proposal is not only unworkable, but will have a detrimental impact on the Association's continuing education activities and those of other specialty societies.

We believe it is next to impossible to keep the identities of speakers, other faculty and potentially participants secret from industry after the funds have been transferred; they may learn who is participating in CME events from brochures, programs, other publications and even physician-employees who participate. The requirement that industry remain unaware of CME participants after the fact is next to impossible in practice, and this will have a direct impact on the Association and ultimately the public whose physicians will not be educated on state of the art medical practices. Local and web-based CMS events are critical to continuing education given the burdens hepatologists face in practice and we believe that limiting their access would be detrimental to these practitioners. Without sponsorships, the Association would be limited in its ability to provide the CME events that our membership requires to maintain their licensure and certifications and to stay on the cutting edge of our field. Under this proposal, AASLD will be forced to limit members' access to these educational sessions because there is no way to prevent industry sponsors to learn of the CME faculty after the fact.

We urge CMS not to implement this provision as written. If CMS feels that some action must be taken with respect to CME, we recommend that the proposal be revised so that the exemption will still apply when a manufacturer provides funding for CME but does not select or pay the speaker or faculty directly or provide the continuing education provider with a distinct, identifiable set of cover recipients to be considered as faculty. Most importantly, CMS must specify that the exemption is satisfied as long as the industry sponsor is unaware of the CME faculty prior to committing to fund the course. We look forward to continuing to work with you finalize these proposals in order to ensure physicians are providing the highest

quality care to Medicare beneficiaries. Thank you again for the opportunity to comment on this proposal. If you have questions or require further information, please contact Erika Miller at 202-484-1100 or emiller@dc-crd.com.

Sincerely,

A handwritten signature in black ink that reads "Heidi Bisognie". The signature is written in a cursive style with a long horizontal flourish at the end.