Bayer HealthCare

Via Electronic Submission

August 29, 2014

Marilyn Tavenner, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244-8016

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 for CY 2015 [CMS-1612-P].

Dear Administrator Tavenner:

Bayer Healthcare LLC (Bayer) appreciates the opportunity provided by the Centers for Medicare and Medicaid Services (CMS or Agency) to submit comments on the Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2015 proposed rule (proposed rule).

With more than 6,000 healthcare employees across the United States, Bayer aims to discover and manufacture products that will improve human health worldwide by diagnosing, preventing and treating diseases. We focus our efforts where we can have the most beneficial impact on the lives of those who depend on over 150 years of our experience researching and developing new pharmaceuticals and medical devices.

On the basis of this long experience, Bayer wishes to comment on several items contained within the proposed rule, which are summarized below:

- **Continued Cuts to Imaging Services**: Bayer is very concerned about the Agency’s continued under-reimbursement for imaging services. Bayer urges CMS to reconsider imaging services rates in light of what is now a long and disturbing history of multiple, drastic cuts.

- **Physician Quality Reporting System (PQRS) Reporting Measures**: Bayer appreciates the continued use of the measures group “Optimizing Patient Exposure to Ionizing Radiation.” These measures will encourage physicians to monitor and consider prior radiation exposure into their clinical decision-making, improving patient health and safety. However, Bayer urges CMS to consider additional measures to capture organ-specific radiation dosing, dosing based on
patient weight, and contrast administration. We believe that these additional measures are essential to adequately addressing the real risk of ionizing radiation exposure. In addition, we urge CMS to establish contrast dose standards in an effort to prevent unnecessary reimaging that exposes patients to needless and excess radiation. Finally, we are opposed to proposed changes that would minimize or eliminate the use of quality measures pertaining to the use of aspirin in a number of specific measures.

- **Contrast Imaging’s New Standard Supply Package**: Bayer is concerned that the contrast imaging supply package is missing supplies. Furthermore, without information on how the prices were assigned, there is not sufficient opportunity to comment in the current proposal.

- **Payment of Secondary Interpretation of Images**: Bayer supports Medicare payment for secondary interpretation of images. We believe the assumption that a single interpretation can satisfy all medically necessary needs is incorrect and inconsistent with current medical practice.

- **Payment for Therapeutic Radiopharmaceuticals in Other Sites of Care**: We ask that CMS clarify that the use of ASP payment policy is allowed in setting reimbursements for therapeutic radiopharmaceuticals in Physician Fee Schedule sites of care, such as freestanding clinics.

- **Multiple Procedure Payment Reduction (MPPR)**: Bayer supports the Agency’s decision to not further expand the MPPR. However, we urge CMS to evaluate the impact of prior reimbursement cuts which have negatively affected beneficiary access and industry innovation.

- **Colorectal Screening**: Bayer fully supports CMS’s proposal to expand access to fecal occult blood test (“FOBT”) screenings, which are a cost-effective and minimally invasive way to screen for colorectal cancer. Bayer encourages CMS to expand coverage of all types of colorectal screening, which may be needed to further investigate a positive FOBT screening.

- **Telehealth Services**: Bayer commends CMS for modifying its definition of rural HPSAs to include more geographic areas, and urges CMS to continue to further expand telehealth services to even more areas in the future to maximize access to health services for patients who may be unable to visit a physician’s office.

- **Open Payments (Sunshine Act)**: Bayer recommends that CMS retain CME exclusion language currently in the final rule. However, it should amend its FAQ requiring that the CME event be accredited by one of the five listed organizations.

I. **Continued Reductions to Imaging Services**

Bayer is very concerned about the Agency’s continued under-reimbursement for imaging services. Imaging reimbursement has been drastically cut fifteen times since 2006.\(^1\) The technical

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\(^1\) See Medical Imaging & Technology Alliance (MITA), Reimbursement & Patient Access, available at: http://www.medicalimaging.org/policy-and-positions/reimbursement/ (last visited August 26, 2014); John Kerry,
component of imaging services based on the volume weighted average for CT and MRI codes has been reduced by 46% from CY 2011 to CY 2014, and these codes see another cut in the proposed rule. Importantly, this analysis does not take into account other reductions, such as those generated by the Multiple Procedure Payment Reduction (MPPR).

We fear that the cuts to reimbursement have jeopardized beneficiary access to imaging services. Imaging services are critical to help reduce overall Medicare costs, as well as protecting beneficiary health outcomes. Bayer urges the Agency to reconsider the reductions in imaging reimbursement in light of these concerns, which are broadly shared by the imaging community.

II. Physician Quality Reporting System (PQRS) Reporting Measures

A. Radiation Dose Tracking

Bayer strongly supports the Agency’s proposal to continue to use the “Optimizing Patient Exposure to Ionizing Radiation” measures. Bayer strongly agrees that it is essential that the Medicare program require tracking and optimization of radiation exposure. Some estimates suggest that in the 1970s and 1980s, medical exposure to radiation accounted for 15% of the total annual average radiation dose – by 2006, medical exposure accounted for 48% of the total. Given these increases, it is critical that patient exposure to radiation be tracked and monitored to prevent excess, unnecessary and entirely avoidable exposure to radiation. In addition, Bayer urges the Agency to require organ-based and patient size-specific radiation dose tracking and appropriate tracking of contrast agent dose exposure. In our view, these additional efforts are essential in order to address the real and growing risk of radiation exposure.

1. Organ-Based Radiation Dose Tracking

Bayer strongly encourages the Agency to add a standard related to organ-specific radiation dose assessment and tracking. Tracking tools that allow providers to assess and track radiation doses applied to different organs is needed to adequately address both patient safety and image quality.

Organ-based dose tracking is important as both the literature and clinical practice clearly establish that specific tissues have different susceptibilities to radiation exposure. Further, these risks vary by gender and age, making this approach essential to furthering the public health initiatives that focus on developing appropriate care for women and the elderly, as underserved populations whose needs have been inadequately addressed by our health care system to date.

Patients’ organ-specific exposure history will be critical to future clinical decision making, especially as many imaging procedures expose multiple sections of the body and organs to


ionizing radiation. This is particularly important, where, for instance, a patient must have repeat diagnostic exposures over time as part of the monitoring of a chronic or progressive disorder. In addition, this approach, and only this approach, to accurate exposure assessment will permit retrospective epidemiological analysis of patient exposures for research purposes. That research can be expected to drive further changes in patient safety measures, protecting patient health and safety.

Where dose indices may provide valuable insight into the variability of scanner parameters and imaging protocols used at a facility, dose indices do not convey patient or organ-specific information that may be used to further refine and limit the usage of ionizing radiation. Thus, we urge CMS to create quality measures based on tracking of organ-based radiation exposure. Organ-based tracking can be achieved using the methods described in the International Commission on Radiological Protection (ICRP) report 103, by manual techniques by a medical physicist, or, ideally, via electronic information systems that compute the equivalent organ doses through automated methods that leverage "Monte Carlo" simulation techniques.

Organ-specific dose assessment is necessary in order to secure an optimization of specific protocol acquisition parameters. This kind of assessment is critical in determining the best methods for optimizing radiation dose to specific tissues that are more radiation sensitive, while maintaining image quality. The equivalent dose concept is used by the medical physics community to describe the amount of radiation absorbed by a mass of tissue and is adjusted based on the energy and type of the ionizing radiation. When considering the type of tissue or organ that is irradiated, a tissue weighting factor (such as that published by the ICRP) is multiplied to the equivalent dose. The effective dose for the entire organism is a summation of the weighted equivalent doses in each organ system.

Significantly, this effective dose computation can serve as an estimate of the biological effect or risk for the entire organism or for a certain organ (if averaged over that particular organ). For example, the corneas are particularly sensitive to radiation exposure, and it is critical to avoid

6 There are many well-known Monte Carlo, or probabilistic methods, for modeling the propagation of x-ray photons through various tissues. Because the physics describing x-ray transport are fundamentally probabilistic in nature, Monte Carlo simulations make many iterative computations using probability distribution functions to vary a number of the parameters guiding the simulation. See M. Cristy, Mathematical Phantoms Representing Children of Various Ages for Use in Estimates of Internal Dose, prepared for the U.S. Nuclear Regulatory Commission (1980) available at http://www.ornl.gov/info/reports/1980/3445605812234.pdf (last visited August 26, 2014).
7 A system, such as Bayer's Radimetrics radiation dose management software, that is able to compute both equivalent and effective dose over the range of the organs actually exposed to radiation from a CT or fluoroscopic x-ray system provides insights for gauging radiation exposure risk. The software matches patient geometry from the imagery to well-validated numerical phantoms and uses the results from Monte Carlo simulations to project radiation exposure at various parts of the anatomy as a function of applied radiation exposure from the imaging equipment. Furthermore, the Bayer software also enables users to gauge the impact of modality equipment protocol variation and patient positioning on radiation and utilization variability. The Bayer Radimetrics package also enables the automation of methods that a medical physicist would need to manually compute. See Adam C. Turner, Maria Zankl, John J. DeMarco et al., The Feasibility of a Scanner-Independent Technique to Estimate Organ Dose from MDCT Scans: Using CTDIvol to Account for Differences Between Scanners, MED. PHYS. 37(4):1816-1825 (2010); W. Huda, A. Sterzik, S. Tipnis, U.J. Schoepf, Organ Doses to Adult Patients for Chest CT, MED. PHYS. 37(2):842-847 (2010).
exposure to prevent early cataract development. For this reason, scans of the cervical neck and perfusion studies must avoid exposing the corneas. Many other clinical examples can be cited. There is a clear need for not only monitoring and minimizing total absorbed dose to the body, but to monitor specific organ doses.

Unfortunately, it is not uncommon for operators of imaging equipment to inadvertently include organs in the scans field of view. The resulting exposure, due to so-called “overscanning,” leads to increased radiation absorption in radio-sensitive organs or tissues. Without organ-based dosimetry methods, a facility will not track the occurrence of “overscans.” Systems and processes to understand the distribution of irradiation in the organs will lead to opportunities for imaging system protocol optimization, training and education to the operators, physicians and physicists. Processes and policies developed to reduce the instance of overscanning, however, require tracking organ-specific exposure.

2. Radiation Dose Adjustments Based on Patient Size

In addition to requiring organ-based tracking, Bayer urges the Agency to consider quality measures that monitor radiation dose exposure adjustments based on patient size. Tracking tools that take into account patient size when calculating radiation exposure levels have the potential to improve patient safety by more accurately calculating the exposure dose for each specific patient. A uniform dosing calculation that does not account for patient size could incorrectly estimate the dose for smaller and larger patients. Even small inaccuracies caused by a uniform exposure estimate could impact a doctor’s decision regarding the benefit risk ratio for additional radiation exposures.

Bayer also advocates the inclusion of Size Specific Dose Estimates (SSDE) in the CT modality specifically. In 2011, standards-based methods for computing SSDE were published by a taskforce that included the American Association of Physicists in Medicine (AAPM) and the International Commission on Radiation Units and Measurements. The report suggests a number of techniques to compute a dose estimate that corrects for patient size and age. Where there are some limitations to the use of the SSDE metrics, they are a more appropriate indicator of patient exposure to ionizing radiation during CT imaging than the dose-index parameters, because they attempt to correct for the size of the patient undergoing CT scanning.

3. Contrast Agent Dose Tracking

In addition to radiation dose tracking, Bayer urges CMS to establish contrast dose standards that: (1) ensure that the provision of contrast agents is weight-based and consistent with FDA approval; and (2) the dose is documented in the appropriate service report. The optimal dose of a contrast agent is needed to prevent unnecessary reimaging that exposes patients to needless and excess radiation. Because the appropriate introduction of exogenous contrast

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10 It is also important to note that Bayer’s radimetric technology enables the reporting and visualization of various unit systems and methods. For example, the Radimetrics software can provide size-specific dose estimates. This is an important capability of any automation tool and we urge the Agency to consider advocating for processes and systems that enable the reporting of various units. We request that the Agency, at a minimum, require facilities to record and track SSDE when comparing the performance across their CT systems. Both of these improvements to longitudinal tracking can be used by both federal facilities and the radiation community to develop improved radiation reference levels.
materials are a critical aspect of achieving diagnostically useful data sets at CT and in many fluoroscopically guided procedures, we urge the Agency to consider the importance of effectively managing and optimizing the delivery of iodinated contrast media.

In many examinations (e.g., CT Angiography), an improperly injected contrast bolus (i.e., too much or too little contrast media) will result in an imaging service which simply cannot be used. In addition, too long or too short of a length of time between the arrival of the contrast bolus and the commencement of the scan will result in a test result that is not usable. In such an instance, patients are subject to a repeat procedure, needlessly increasing their radiation exposure.

Contrast agents are drugs that are regulated by the FDA with specifically approved indications and important safety information. Nonetheless, the use of contrast agents is rarely, if ever, documented, resulting in no method to track how much has been administered to a patient and whether such administration is appropriate and accurate. In general, we are not aware of any other drug that is administered with the same lack of monitoring and oversight. This aberrational omission from radiology reports must be addressed to ensure patient health and safety.

Accordingly, we believe that it is essential that the Agency add a standard that ensures that facilities adopt technologies and techniques for the review of on-label contrast administration and institute electronic systems that capture contrast administration data and suggest appropriate contrast use. Such contrast administration data, which should include contrast volume and concentration, should be required to be listed in the final radiology interpretive report to ensure the information is appropriately documented and to ensure future providers can review past use. In the absence of this, a substantial cause of unnecessary radiation exposure will be left unaddressed. Tools currently exist to improve contrast tracking and administration, and Bayer urges the Agency to institute a quality measure to make use of these technologies and techniques.

B. Quality Measures Pertaining to Appropriate Aspirin Use

Bayer is concerned about some changes that would minimize or eliminate the use of quality measures pertaining to the use of aspirin in a number of specific situations as proposed by CMS. Specific areas of concern relate to the use of aspirin in select patients with hypertension or ischemic vascular disease and those who have experienced an acute myocardia

1. Hypertension: Use of Aspirin or Other Antithrombotic Therapy:

Bayer is opposed to the removal of the measure to assess the “Percent of patients aged 30 through 90 years old with a diagnosis of hypertension and are eligible for aspirin or other antithrombotic therapy who are prescribed aspirin or other antithrombotic therapy.” The preventive effects of aspirin in patients at moderate to high risk of an ischemic cardiovascular (CV) event (of which hypertension contributes to the overall risk) are well accepted. With regard to aspirin use in hypertensive patients, there are guidelines that recommend its use to prevent CV events in at-risk patients when BP is controlled. 11 We believe that “eligible for

aspirin therapy” implies that the patient is at risk of a CV event, and because aspirin is generally recognized globally as cornerstone therapy for preventing CV ischemic events, it is more than reasonable to track its usage in at-risk patients as a quality assurance measure.

2. Aspirin Upon Arrival: Removal of Measure from Hospital OQR Program:

The Hospital OQR Program provides financial incentives for hospitals to report quality of care measure data and penalizes hospitals for failing to report or meet specified standards. Bayer is opposed to the CMS proposal to remove tracking aspirin provided at arrival as part of the Hospital OQR Program. Studies have concluded that aspirin after a myocardial infarction is critical to ensuring patient recovery. In addition to continued incentives for hospitals to ensure patients receive potentially life-saving treatment, maintaining the measure provides CMS with data that helps Medicare beneficiaries make informed decisions about their healthcare options.

Additionally, the Affordable Care Act requires most health plans to provide coverage for aspirin “without cost sharing only when prescribed by a healthcare provider.” Requiring hospitals to report on this aspirin measure will continue to make providers more likely to provide patients with written instructions. In turn, research clearly indicates that patients are more likely to comply with written instructions, such as a prescription, as opposed to a verbal recommendation.

3. Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic:

Multiple guidelines from several organizations support the use of aspirin in a variety of acute coronary settings. Therefore, Bayer supports maintaining the inclusion of a measure to evaluate the “Percentage of patients 18 years of age and older who were discharged alive for AMI, coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of IVD during the measurement period and who had document of use of aspirin or another antithrombotic during the measurement period.” Aspirin is recommended by organizations including the American College of Cardiology, American Hospital Association, European Society of Cardiology (ESC) and the National Institute for Health and Clinical Excellence (NICE) for use in acute cardiac situations including acute coronary syndrome (ACS), evolving myocardial infarction, and percutaneous coronary interventions (PCI). Specific to PCI, recommendations from the 2005

12 Federal Register Vol. 79, No. 133, July 11, 2014; Proposed Rules, page 40429
14 See CMS.gov, Hospital Outpatient Quality Reporting Program, Access August 5, 2014 at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalOutpatientQualityReportingProgram.html (last visited August 26, 2014).
15 Department of Labor, Department of Health and Human Services, Department of the Treasury. FAQ about Affordable Care Act Implementation Part XII.
and 2010 ESC guidelines\textsuperscript{17} as well as the 2011 ACC/AHA guidelines\textsuperscript{18} include use of aspirin prior to PCI and to be continued indefinitely after the procedure. Additional guidelines are also applicable to further support aspirin use in acute coronary settings\textsuperscript{19} and aspirin use postsurgery\textsuperscript{20}.

\section*{III. Contrast Imaging's New Standard Supply Package}

Bayer is concerned that the proposed list of supplies in CMS' proposed contrast imaging standard supply package does not adequately capture all the supplies typically used in both CT and MRI, especially with power injection.\textsuperscript{21} CMS' proposal follows the RUC recommendation of creating a new direct PE input standard supply package "Imaging w/contrast, standard package" for contrast enhanced imaging. While the current proposal includes some necessary items, it appears to leave out others typically used and does not account for differences in supply use.

For example, the list does not include single saline syringes, the items needed to keep the IV in place during an injection, such as tape and adhesive dressings, or the 2x2 used when the IV is removed. Many providers use power injectors, which would also require the use of a syringe kit, including saline and a saline syringe. In some instances, such as when there is no existing IV, a butterfly needle would be used instead of the angiocatheter. In general, CMS' proposed package more closely aligns to manual administration, not power injection. However, power injection is predominantly used by providers performing CT services with IV contrast.\textsuperscript{22} Thus, it is critical that the supply package include supplies associated with power injection.

Furthermore, CMS provides no details on how the price for the standard supply package was established. Without additional details, finalization of this proposal would not be appropriate, as commenters have not been given adequate notice and opportunity to comment as required under the Administrative Procedure Act (APA).\textsuperscript{23}

\section*{IV. Payment of Secondary Interpretation of Images}

Bayer supports Medicare payment for secondary interpretation of images. We agree with the Agency's statement that technological advances have enabled greater sharing of images

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\textsuperscript{21} Power injectors are clearly the standard of care, at least in CT services.
\textsuperscript{23} 5 U.S.C. § 553.
\end{flushright}
between providers. The use of imaging technology to share images is an important advancement that has the ability to improve quality of care and reduce unnecessary imaging services.

The existing system often fails to provide reimbursement for a second interpretation on the same image, even though different providers make medically necessary use of an image at different points in the care continuum or even in addressing different clinical issues. As a result, providers may be incentivized to perform multiple, unnecessary procedures, subjecting patients to needless radiation. Allowing payment for secondary interpretation of images would ensure alignment of incentives, ensure that appropriate payment is provided, reduce radiation exposure, and save the costs associated with repeat technical component procedures.

V. Payment for Therapeutic Radiopharmaceuticals in Physician Fee Schedule Sites of Care

Similar to how therapeutic radiopharmaceuticals are reimbursed in the hospital outpatient department setting and how other drugs are reimbursed in the Physician Fee Schedule sites of care, therapeutic radiopharmaceuticals should be reimbursed using the ASP payment policy in the Physician Fee Schedule sites of care, such as freestanding clinics. This method is consistent with the statute for products approved after the date that the Medicare Modernization Act (MMA) was enacted. We also believe that ASP-based reimbursement for therapeutic radiopharmaceuticals is good policy, because ASP-based reimbursement would allow the Medicare program to have an alternative in the Physician Fee Schedule sites of care to AWP-based reimbursement, which it disfavors, and to invoice-reimbursement, which has needless processing complexity and cost for both the Medicare program and providers. Further, we are aware that some MACs have issued guidance stating that therapeutic radiopharmaceuticals will be reimbursed using ASP, when voluntarily reported. CMS revised the reporting requirements to accommodate patient-ready dose ASP reporting for radiopharmaceuticals, and has stated many times that ASP is the most transparent payment methodology. Using ASP data is consistent with CMS’s overall goals. Thus, we recommend CMS clarify the use of ASP payment is appropriate for therapeutic radiopharmaceuticals in the Physician Fee Schedule sites of care.

VI. Multiple Procedure Payment Reduction (MPPR)

Bayer supports the Agency’s decision to not expand the MPPR program at this time. It is important for the Agency and stakeholders to assess the impact of a host of prior cuts on patient access to important diagnostic procedures. Bayer continues to believe that any further reductions in payment for imaging services creates an unacceptable risk of undermining beneficiary access to diagnostic imaging services.

VII. Colorectal Screening

To continue its provision of encouraging beneficiaries to be screened for colorectal cancer, CMS is seeking to include screening colonoscopies as a “colorectal cancer screening test.” However, continuing to require Medicare beneficiaries to bear the deductible and coinsurance expenses for separately billed anesthesia services furnished and covered by Medicare in conjunction with screening colonoscopies could become a significant barrier to these essential preventive services. In order to carry out its goal of providing preventive services, CMS proposes to waive the coinsurance and deductible to the anesthesia or sedation services.
furnished in conjunction with colonoscopies. Bayer strongly supports this move on the part of CMS to further needed screening regimens but also to ensure beneficiary access based on cost.

VIII. Telehealth Services

Bayer strongly supports telehealth services as a cost-effective and convenient way to improve access to healthcare services and fully supports the proposal to revise the definition of rural health professional shortage areas (HPSAs) to “census tracts classified as rural by the Office of Rural Health Policy.” Bayer also supports the Agency’s proposal to determine an originating site’s geographic eligibility on an annual basis.

Bayer commends CMS for modifying its definition of rural HPSAs to include more geographic areas. Bayer urges CMS to continue to further expand telehealth services to even more areas in the future to maximize access to health services for patients who may be unable to visit a physician’s office, as research has shown that such services improve patient outcomes.²⁴

Bayer believes that telehealth technology provides CMS with a way to increase patient access to effective medical care while minimizing increased cost, particularly as broadband internet access across the nation improves. Telehealth technology is of particular importance to certain Medicare populations, such as seniors facing mobility challenges or others who are located in rural areas, and we encourage the Agency to continue to seek ways to help these patients access medical care through expanded telehealth services.

IX. Open Payments (Sunshine Act): Proposal to Eliminate Payments Associated with Certain Continuing Medical Education Events

Section 6002 of the Affordable Care Act, “Transparency reports and reporting of physician ownership or investment interests” (Sunshine Act)²⁵ exempts from reporting as a payment or transfer of value compensation received by a covered recipient for speaking at a continuing medical education (CME) program, so long as certain specified criteria are met. This includes meeting accreditation or certification requirements by one of five entities specified in the rules. In addition, covered recipients must not be selected by or paid directly by the manufacturer nor can the manufacturer set the criteria for speaker selection.²⁶ Furthermore, CMS explained in an FAQ that accreditation must be granted by one of the five bodies cited in the rule.²⁷

CMS has recognized the important role that accrediting and certifying bodies as well as industry standards for commercial support offer, creating “important and necessary safeguards

²⁶ 42 C.F.R. § 403.904(g)(1).
²⁷ FAQ No. 8398 (“[T]he list of accrediting or certifying bodies in the final rule at 42 CFR § 403.904(g)(1)(i) is exhaustive; in order to qualify for the exclusion . . . CME events must be run by CME providers that are accredited or certified by one of the accreditation or certification entities in § 403.904(g)(1)(i) and, accordingly, meet the accreditation or certification requirements and standards of any of those specific entities. Payments to speakers at CME events that are not run by CME providers accredited or certified by one of the entities in § 403.904(g)(1) . . . are reportable payments or other transfers of value for Open Payments.”
prohibiting the involvement of the sponsor in the educational content.”28 In addition, CMS noted “unaccredited and non-certified education,” did “not require the same safeguards.”29 Thus, CMS has stated that industry support of CME meetings that meet the criteria set forth in the rule would “not be considered indirect payments or other transfers of value for purposes of reporting [and] the awareness standards for indirect payments are not applicable to such support.”30

However, CMS is now proposing to eliminate this exclusion in an effort to remove redundancy with the separate exclusion for certain indirect payments (42 C.F.R. § 403.904(i)(1)), and to address the concerns of some that CMS is endorsing certain organizations that sponsor CME events. CMS notes that in the event of the CMS removal of this exclusion, there would still not be a requirement to report a grant to a CME provider if: (1) the covered recipient is not selected or paid directly by the applicable manufacturer; and (2) the applicable manufacturer does not provide the CME provider a distinct, identifiable set of covered recipients for selection as speakers.31

Bayer does not believe the current exclusions for accredited CME (42 C.F.R. § 403.904(g)) and certain indirect payments (42 C.F.R. § 403.904(i)(1)) are redundant and therefore recommends that they be maintained. In the case of indirect payments, an exclusion is provided when the manufacturer is “unaware” or does not know the identity of the covered entity during the reporting year or by the end of the second quarter of the following reporting year.32 The exclusion for accredited CME does not include the same “awareness” standard. Instead, it reflects that sponsorship of CME is “unique” noting that sufficient safeguards are present with accredited or certified CME. In this case, the accredited CME provider’s independence alters these value transfers. As such, the independent organization acts as an intermediary, interrupting the chain of interactions. Thus, the transfers no longer flow “from” an applicable manufacturer “to” a covered recipient.

Thus, Bayer recommends that CMS retain the language of the CME exclusion currently in the final rule in § 403.904(g) but amend its FAQ requiring that the CME event be accredited by one of the five listed organizations. This could be readily accomplished by either adding “or any other national or state accrediting body” to the current list of organizations or, if CMS would prefer that the regulation not name any accrediting bodies, simply require that the CME event be offered by an organization “accredited by a national or state accrediting body”.

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28 Id.
29 Id.
30 Id.
32 42 C.F.R. § 403.904(i)(1).
Bayer appreciates the opportunity to comment on the proposed rule and looks forward to working with CMS in the future to improve access to quality, affordable healthcare coverage.

Sincerely,

Raymond F. Kerins, Jr.
Senior Vice President
Head of Communications,
Government Relations & Policy