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August 30, 2011

Donald M. Berwick, MD, MPP

Administrator

Centers for Medicare & Medicaid Services

Attention: CMS-1524-P

Room 445-G, Hubert H. Humphrey Building

200 Independence Avenue, SW

Washington, DC 20201

Re: Medicare Program; Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2012

Dear Dr. Berwick:

On behalf of the more than 75,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments to the proposed rule: *Medicare Program; Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2012* (Proposed Rule) that was published in the *Federal Register* on July 19, 2011. The ACS is a scientific and educational association of surgeons, founded in 1913, to improve the quality of care for the surgical patient by setting high standards for surgical education and practice. Our comments on issues of interest to ACS are presented in the order in which they appear in the Proposed Rule.

POTENTIALLY MISVALUED SERVICES UNDER THE PHYSICIAN FEE SCHEDULE

Calendar Year (CY) 2012 Identification and Review of Potentially Misvalued Services

In the Proposed Rule, the Centers for Medicare & Medicaid Services (CMS) states that for CY 2012, the Agency is continuing with the work to identify and review additional services under the potentially misvalued codes initiative. As such, CMS developed two code lists of potentially misvalued codes that it proposes to refer to the American Medical Association Relative Value Scale Update Committee (AMA RUC) for review: a list of 70 Physician Fee Schedule (PFS) high expenditure codes and a list of 91 Evaluation and Management (E/M) codes. To develop a robust and representative list of codes for review under the potentially misvalued codes initiative, CMS examined the highest PFS expenditure services by specialty and identified those that have not been reviewed since CY 2006 (the year CMS completed the Third Five-Year Review of Work and before the Agency began its potentially misvalued codes initiative)> CMS proposed the review of the E/M codes due to the fact that the last review was in CY 2006.

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Dr. Berwick
August 30, 2011
Page 2

The ACS would like to point out that the Five-Year Review of Work is a statutory process implemented to review codes that may be potentially misvalued and that 2006 was not the start of this initiative. In fact, the AMA RUC suggested and developed the process of a *continuous* review of potentially misvalued codes instead of waiting until a scheduled Five-Year Review of Work. This AMA RUC work started in 2006 with the creation of the AMA RUC Five-Year Review Identification Workgroup (now called the Relativity Assessment Workgroup).

Evaluation and Management Codes Referred For AMA RUC Review

In the Proposed Rule, CMS notes that: "E/M services consistently appeared in the top 20 high PFS expenditure services. We noted as well that most of the E/M services have not been reviewed since the comprehensive review of services for the Third Five-Year Review of Work in CY 2006."¹ Based on this assessment, CMS has requested a comprehensive review of all E/M codes.

The rationale for this review is based on the determination that since 2005,

there has been significant interest in delivery system reform, such as patient-centered medical homes and making the primary care physician the focus of managing the patient's chronic conditions. The chronic conditions challenging the Medicare population include heart disease, diabetes, respiratory disease, breast cancer, allergy, Alzheimer's disease, and factors associated with obesity. Thus, as the focus of primary care has evolved from an episodic treatment-based orientation to a focus on comprehensive patient-centered care management in order to meet the challenges of preventing and managing chronic disease, we believe a more current review of E/M codes is warranted.²

The ACS requests that CMS reconsider its directive for review of all E/M codes because the current E/M codes, as written, do not correspond to the work associated with patient-centered care management. We note that there are many Current Procedural Terminology (CPT) codes that have been reviewed and valued by the AMA RUC for such services including: medical team conference, comprehensive preventive evaluation, physician supervision of a hospice patient, international normalized ratio management, smoking and alcohol counseling, and phone or electronic evaluation. None of these services is covered by Medicare, yet many of these services are part of a patient-centered care management model and are important components of necessary services for managing patients with chronic conditions.

¹ 76 Fed. Reg. 42,793 (Jul. 19, 2011).

² *Id.*



Dr. Berwick
August 30, 2011
Page 3

Additionally, in 2008, the RUC spent significant time and effort responding to a CMS request to develop a payment model for the medical home. A final product was delivered to the Agency, but never implemented.

The ACS agrees that the frail elderly with chronic diseases would be well served to have a provider to assist with managing their care, but this care would be better described by new codes, and not the current E/M codes. Additionally, we believe that the new codes should bundle services and include a global period, because just as a surgical patient requires global care, the medical patient with chronic diseases also requires global care. A successful example of payment for chronic disease management using a global period is the family of end stage renal disease codes, which have a global period of 30 days.

The current E/M codes have been reviewed and refined through two separate Five-Year Review of Work processes, resulting in a shift of billions of dollars from procedures to E/M services. This significant shift of money has not markedly improved the provision of care or the health of our nation, and a further shift of money away from procedures may result in the unintended consequence of negatively impacting care for the surgical patient. We believe these E/M codes are valued appropriately for the work that is described. We disagree with CMS that these codes should be reviewed again because they do not reflect current medical practice, and instead suggest that CMS request that stakeholders work with the CPT Editorial Panel and the AMA RUC to create and value new bundled codes for chronic disease management. We also suggest that CMS examine existing CPT codes that have been recently reviewed by the AMA RUC for services that complement E/M codes such as telephone and electronic evaluation.

Select List of Procedural Codes Referred for AMA RUC Review

In Table 7 of the Proposed Rule, CMS identifies 70 high volume codes as potentially misvalued under the seventh statutory category, "other codes determined to be appropriate by the Secretary."³ CMS selected these codes based on the fact that these codes "have not been reviewed for at least 6 years, and in many cases the last review occurred more than 10 years ago. They represent high Medicare expenditures under the PFS; thus, we believe that a review to assess changes in physician work and update direct PE inputs is warranted."⁴ Below, we address three of the codes in Table 7 that are performed by general surgeons: 47562, 47563, and 49505.

³ *Id.* at 42,794.

⁴ *Id.*



Dr. Berwick
August 30, 2011
Page 4

Code 47563, (Laparoscopy, surgical; cholecystectomy with cholangiography) was just reviewed in 2010 and discussed in the Five-Year Review of Work proposed rule that was published in the *Federal Register* on May 26, 2011. The ACS has already submitted a comment to CMS regarding this code and expects to discuss it during the refinement panel process. We believe the inclusion of this code on Table 7 was an error.

Codes 47562 (Laparoscopy, surgical; cholecystectomy) and 49505 (Repair initial inguinal hernia, age 5 years or older; reducible) were reviewed as recently as 2005 at the request of CMS as potentially misvalued codes. Subsequent to that review, CMS determined that the current work RVUs were correct.⁵

All three codes have recently been reviewed at the request of CMS and the work to perform these services has not changed in the past five years. Based on this information, along with the fact that these codes have been reviewed multiple times over 20 years as potentially misvalued, we request CMS remove these three codes from the list of codes that would require another AMA RUC review.

Codes Potentially Requiring Updates to Physician Work

CMS states that it received a public comment regarding a rank order anomaly of the work RVUs for codes 47600 (Cholecystectomy) and 47605 (Cholecystectomy; with cholangiography). Further, CMS states that that the difference in physician time and number of visits is the cause for the difference in work RVUs for these codes, where code 47600 should not have more time and visits associated with the service than code 47605. CMS is requesting that the AMA RUC review both codes.

First, we note that accepting this public comment outside of a formal request for public comment is not consistent with previous CMS policy. We acknowledge that CMS has proposed a public process for the nomination of potentially misvalued codes in this Proposed Rule, but CMS has not yet finalized that process. We also note that for codes cited as having a rank order anomaly, CMS has specifically indicated that "the commenter would need to assemble evidence on service time, technical skill, patient severity, complexity, length of stay and other factors for the code being considered and the codes to which it is compared. These reference services may be both inter- and intra-specialty."⁶ We do not believe the commenter included any of this information, so CMS has essentially accepted a comment that does not meet its own proposed policy.

⁵ Medicare Program; Five Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology, available at <http://www.cms.gov/physicianfeesched/pfsfrn/itemdetail.asp?itemid=CMS1183724>.

⁶ 76 Fed. Reg. 42,792 (Jul. 19, 2011).



Dr. Berwick
August 30, 2011
Page 5

However, we do not disagree that there is a work RVU rank order anomaly between codes 47600 and 47605. We believe that the misvalued code is 47605 and not 47600. We draw this conclusion from the fact that code 47600 was reviewed in 2005 at the request of CMS as a potentially misvalued code. Subsequent to that review, an increase in work RVUs was accepted by the AMA RUC and CMS based on compelling evidence of a change in patient population. Code 47605 was not opened for review in 2005 because one of the policies for a specialty reviewing a code during the Five-Year Review process is that it had not previously been reviewed, and this code did not meet this requirement. We accept CMS' request to review both codes again with the understanding that we are validating code 47600 as correct and providing more current information for code 47605 relative to code 47600.

QUALITY REPORTING INITIATIVES

Physician Payment, Efficiency, and Quality Improvements – Physician Quality Reporting System

CMS proposes to allow the medical specialty boards to determine what qualifies as more frequent participation for a specific program element for their physicians, and we support this proposal to provide greater deference to the specialty boards. Medical specialty boards are uniquely qualified to determine what specifically can be considered more frequent participation. Because different specialties have various certification requirements, each specialty board should be able to determine whether the “more frequently” requirement has been met for their physicians, and we encourage CMS to avoid making any uniform prescriptive requirements across specialty boards.

CMS has received several requests to revise the criteria for satisfying the Maintenance of Certification (MOC) Program incentive set forth in the CY 2011 PFS. CMS has proposed to now interpret this provision more broadly by allowing the requirement that a physician “more frequently than is required to qualify for or maintain board certification status must participate in such a Maintenance of Certification Program” to apply to the program as a whole. We believe that a reasonable interpretation of this provision suggests that each of the various components of the MOC program does not need to be performed more frequently. Instead, any element that is performed more frequently than is required satisfies the entire requirement. MOC programs require that a physician:

- maintain a valid, unrestricted medical license in the United States;
- participate in educational as well as self-assessment programs that require an assessment of what was learned;



Dr. Berwick
August 30, 2011
Page 6

- demonstrate, through secure examination, that the physician has medical knowledge, fundamental and diagnostic skills, and clinical judgment to provide quality care in their respective specialty; and
- successfully complete a qualified Maintenance of Certification Program practice assessment.

CMS states that “the ‘more frequently’ requirement does not apply to the first part, which states that a physician maintain a valid unrestricted license, as there is no way that a physician may maintain a valid unrestricted license ‘more frequently.’ As such, we [CMS] believe that the more frequently requirement could be satisfied based on any of the other elements of the program (that is educational and self assessment program, secure examination, and practice assessment).”⁷ While the ACS understands that in order to earn the 0.5 percent incentive for 2012-2014, an eligible professional must participate more frequently than is required in only one of these remaining three elements, we view that participating more frequently than is required would not be applicable to the third element, secure examination. Current board requirements for most organizations only require the secure examination every ten years. While some boards require examinations more frequently, it is still over the course of several years and applying the “more frequently than is required” in the context of an annual payment update does not make sense when applied to the secure examination element.

Incentives and Payment Adjustments for Electronic Prescribing (eRx) – The Electronic Prescribing Incentive Program

In the CY 2011 PFS Final Rule, CMS established the criteria for being a successful electronic prescriber for the 2011 payment *incentive* and for the 2013 payment *adjustment* based on a 12-month reporting period in 2011. In order to create more opportunities for eligible professionals to avoid the 2013 and 2014 payment *adjustments*, CMS proposes six-month reporting periods in which an eligible professional can avoid the payment adjustment if he or she reports, at least 10 times, a prescription for a Medicare Part B patient during an encounter that was transmitted electronically using a qualified electronic prescribing system (January 1, 2012 to June 30, 2012 for the 2013 payment *adjustment* and January 1, 2013 to June 30, 2013 for the 2014 payment *adjustment*). The ACS supports CMS’ proposal for the years 2013 and 2014 to add an additional six-month reporting window.

During the proposed six-month reporting period, CMS would no longer require that the electronic prescription be associated with one of the denominator codes, and we support this proposal. While we understand that CMS has already finalized the 2013 payment adjustment process, we believe that CMS could easily also apply this same policy to the 12-month reporting period. Furthermore, the

⁷ Id. at 42,881.



Dr. Berwick
August 30, 2011
Page 7

ACS believes that because the value of office visits during a global period are essentially associated with denominator codes, CMS should consider including global periods for surgeons in which office visits listed in association with denominator codes are already built into the global period even during the 12-month reporting period. The ACS acknowledges that the codes need to be part of an outpatient service and is willing to provide additional information about what is incorporated into particular globals on request.

CMS proposes to include the following hardship exemptions in 2013 and 2014: (1) inability to electronically prescribe due to local, state, or federal law or regulation; and (2) eligible professionals who prescribe fewer than 100 prescriptions during a six-month payment adjustment reporting period. The ACS supports both of these hardship exemption categories.

As we previously stated in our comments to the *Proposed Changes to the Electronic Prescribing (eRx) Incentive* proposed rule published in the *Federal Register* on June 1, 2011, the ACS supports the hardship exemption for the inability to electronically prescribe due to local, state, or federal law or regulation. The ACS agrees with CMS that without this exemption, eligible professionals face a significant hardship because many eligible professionals who meet the threshold of 10 percent of their Medicare claims based on the list of denominator codes, do not have adequate opportunities to meet the eRx requirements due to local, State, or Federal laws. In addition, we stated that we continue to support the proposed hardship exemption related to those eligible professionals who register to participate in the EHR Incentive Program and adopt certified EHR technology, but may have delayed adoption of eRx technology until the list of certified EHR technology became available and recommend that CMS continue this hardship exemption. We also urge CMS to keep the process of requesting a hardship exemption of as little burden as possible and to establish a Web-based portal for reporting.

Medicare EHR Incentive Program for Eligible Professionals for the 2012 Payment Year

CMS has not yet developed a Web-based portal for EHR certification and the Agency still requires eligible professionals to submit a paper EHR Incentive Payment Program attestation. This is a burdensome process, and we urge CMS to develop a Web-based portal as expediently as possible. The ACS believes that paper-based submission for meaningful use attestation would be particularly burdensome, especially in light of the numerous other applications and reporting requirements associated with other CMS programs.



Dr. Berwick
August 30, 2011
Page 8

IMPROVEMENTS TO THE PHYSICIAN FEEDBACK PROGRAM AND ESTABLISHMENT OF THE VALUE-BASED PAYMENT MODIFIER

Physician Feedback Program

The purpose of the Physician Feedback Program is to provide confidential reports to physicians that measure the resources involved in furnishing care to Medicare beneficiaries. CMS states that it plans to examine alternative attribution methods that would allow more Medicare beneficiaries to be matched to physicians for purposes of assessing the quality of care furnished and the associated resources. We reiterate our comments from previous years that any attribution methodologies used for the Physician Feedback reports must be transparent. We recommend that the entire algorithm used to generate the reports be in the public domain, along with clear plans for evaluating the impact of the reports. We also stress the necessity of risk adjustment, which should include the recognition that a patient population's socioeconomic factors and co-morbidity can have an impact on achieving ideal patient outcome goals.

CMS also plans to work to identify quality measures appropriate to the practices of specialists who perform surgical procedures or interventions, especially those procedures that are high volume and/or high cost. The PQRs and claims-based measures listed in Table 61 of the Proposed Rule that CMS plans to use for Phase III of the Physician Feedback reports are generally not measures used for measuring surgical care. Working collaboratively with CMS, the ACS National Surgical Quality Improvement Program (NSQIP) staff has developed the following five surgery-related outcomes-based quality measures that CMS could consider including in the Physician Feedback program:

1. A risk adjusted vascular surgery lower extremity bypass measure;
2. A risk and procedure mix adjusted surgical site infection (SSI) measure;
3. A risk and procedure mix adjusted urinary tract infection (UTI) measure;
4. A colon resection outcomes measure; and
5. A risk and procedure mix adjusted elderly surgery measure, which evaluates the outcomes of all procedures performed in a facility for persons 65 years and older.

The lower extremity bypass measure, the colon resection measures, and the elderly surgery measure have been endorsed by the National Quality Forum (NQF). The SSI and UTI measures are currently undergoing the endorsement process at the NQF. We support measures including the five listed above and other ACS NSQIP outcomes measures as they have increased clinical validity and are proven measures for evaluation and improvement of surgery quality. We would be pleased to work with CMS to identify additional measures appropriate for the Physician Feedback program as it applies to surgery.



Dr. Berwick
August 30, 2011
Page 9

CMS also states that it anticipates using Physician Feedback reports in future years as the testing basis to develop and implement the value-based payment modifier. We are concerned with the proposed linking of the value-based payment modifier and the Physician Feedback program without additional analysis of these programs. The value-based payment modifier is still in its infancy, and it is unclear at this stage how it will be implemented, especially in light of the hurdles associated with attributing care to a single physician and the effects of delivering complex care involving teams of physicians. The Physician Feedback program itself has not been adequately tested, and relatively few physicians received feedback reports as part of Phases I and II. Perhaps at some later date it would make sense to link the two programs together, but until more is learned about each, we have strong concerns with the current proposal to utilize the Physician Feedback reports as a foundation for implementing the value-based payment modifier.

CMS also indicates that the Agency is moving forward with the development of the Medicare-specific episode grouper. We urge CMS to be more transparent regarding the development of the Medicare-specific episode grouper by sharing relevant information with stakeholders via Open Door Forums, Town Hall Meetings, and/or Listening Sessions, rather than only through notice and comment rulemaking. This episode grouper, once implemented, will affect quality measurement and reimbursement of all physicians, so it is important that stakeholders are kept abreast of its progress.

Value-Based Payment Modifier

The ACA requires CMS to establish a payment modifier that provides for differential payment to physicians under the physician fee schedule to reflect “value,” which the Proposed Rule describes as the quality of care compared to cost. The value-based modifier is independent from the geographic adjustments applied under the fee schedule, and will be implemented in a budget-neutral manner. Table 62 of the Proposed Rule lists proposed quality measures for the value-based payment modifier, which will be implemented starting in 2015. Similar to the measures described above for the Physician Feedback Program, the measures in Table 62 are not used for measuring surgical care. We recommend that CMS consider the inclusion of the aforementioned surgery measures, and we would be pleased to work with CMS to develop a list of appropriate measures for use in the application of the value-based payment modifier to surgery.

BUNDLING OF PAYMENTS FOR SERVICES PROVIDED TO OUTPATIENTS WHO LATER ARE ADMITTED AS INPATIENTS: 3-DAY PAYMENT WINDOW POLICY AND THE IMPACT ON WHOLLY OWNED OR WHOLLY OPERATED PHYSICIAN PRACTICES

CMS proposes that, starting on January 1, 2012, when a physician furnishes services to a Medicare beneficiary in a hospital’s wholly owned or wholly operated physician practice and the beneficiary is



Dr. Berwick
August 30, 2011
Page 10

subsequently admitted as an inpatient to the parent hospital within three days, the “three-day payment window” policy will apply. This means that all diagnostic services furnished in the three days prior to admission and any nondiagnostic services that are clinically related to the reason for the patient’s inpatient admission will be paid at the facility rate, or the physician will be paid only the professional component if the service has a technical component/professional component split.

We agree with CMS that it is reasonable to apply this policy to wholly *owned* physician practices, but we are concerned about the application of the policy to practices that are only wholly *operated* by a hospital. This policy assumes that physician practice losses can be transferred to the hospital, which is not always the case if a practice is wholly operated, but not wholly owned because a practice may be wholly operated yet financially separate and distinct from the hospital. Thus, the application of this policy to wholly *operated* physician practices that are financially independent of the hospital that operates the practice would be inappropriate.

In addition, we request that CMS identify the physician practices that would be affected by this provision and make this information available to these practices. Physician practices must have the opportunity to review and validate whether they are wholly owned or operated according to CMS data, prior to implementation of the payment adjustments.

We also request that CMS delay the implementation of this provision by one year, to begin on January 1, 2013. We question whether hospitals have the necessary systems in place to identify whether a beneficiary was seen at a physician’s office prior to admission as an inpatient and to communicate that information to the physician practice. A reliable system is critical as physicians who are not informed by the hospital that their services fall into the three-day payment window will have no way of avoiding inadvertent overbilling for those services.

While we believe hospitals will need an additional year to prepare for the implementation of this policy, we also believe a delay is necessary to afford CMS time to clarify the meaning of “clinically related” as it applies to this proposal. While we understand that an exact ICD-9-CM diagnosis code match for the outpatient encounter and the inpatient stay is no longer required, we request further guidance on how the term “clinically related” will now be interpreted. We believe a longer delay might be necessary if CMS does not clearly define the term “clinically related,” which is central to this policy, in time for a January 1, 2013 implementation date.



Dr. Berwick
August 30, 2011
Page 11

We appreciate the opportunity to provide comments regarding this Proposed Rule. If you have any questions about our comments, please contact Bob Jasak Assistant Director for Regulatory and Quality Affairs in our Division of Advocacy and Health Policy. He can be reached at bjasak@facs.org or at (202) 672-1508.

Sincerely,

A handwritten signature in black ink that reads "David B. Hoyt". The signature is written in a cursive, slightly slanted style.

David B. Hoyt, MD, FACS
Executive Director