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September 5, 2013

Ms. Marilyn B. Tavenner

Administrator

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Attention: CMS-1600-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 & Other Revisions to Part B for CY 2014

Dear Ms. Tavenner:

On behalf of the more than 79,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments to the proposed rule: *Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014* (Proposed Rule) that was published in the *Federal Register* on July 19, 2013. 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.

PROVISIONS OF THE PROPOSED RULE

Resource-Based Practice Expense Relative Value Units

Using OPPS and ASC Rates in Developing PE RVUs

In the proposed rule, the Centers for Medicare and Medicaid Services (CMS) indicates that for some services, the total Medicare payment when the service is furnished in the physician office setting exceeds the total Medicare payment when the service is furnished in a hospital outpatient department (OPD) or ambulatory surgical center (ASC). Therefore, CMS proposes a change in the practice expense (PE) methodology beginning in calendar year (CY) 2014 that would limit the non-facility PE Relative Value Units (RVUs) for a list of over 200 codes to the current year's Outpatient Prospective Payment System (OPPS) or ASC rates so that the total non-facility Physician Fee Schedule



(PFS) payment amount would not exceed the total combined amount that Medicare would pay for the same code in the facility setting. In addition to other exceptions, CMS proposes to exempt codes with low volume in the OPPS or ASC. “Low volume” is defined as when five percent or less of the total number of services are furnished in the OPPS setting relative to the total number of PFS/OPPS allowed services.

Although we are not commenting on any of the codes that would be impacted by this policy, we provide comments on this proposal generally and believe the rationale behind the proposed methodology is flawed. We believe that the implementation of this proposal would lead to inappropriate PE valuation and payment. In addition, this policy would distort current data inputs and result in inaccuracies in the data used to develop Medicare payments. **As such, we urge CMS not to implement this proposed policy that would revise PE values by capping non-facility PE RVUs at either the OPPS or ASC facility payment levels.**

CMS states that the difference in the facility vs. the non-facility payments is due to anomalies in the data used under the PFS and in the application of its resource-based PE methodology to these particular services. We disagree because we maintain that the process used by the American Medical Association’s Relative Value System Update Committee (RUC) to evaluate PE inputs is thorough and data-driven. The RUC devotes considerable time to the appropriate evaluation of recommended PE staff type, supplies, and equipment. In addition, given the RUC’s multidisciplinary resources and history of expertise in this arena, the RUC is clearly the entity in the best position to evaluate PE inputs.

CMS also states that the PFS methodology suffers from incomplete, small sample, potentially biased, or inaccurate resource input costs that can often be outdated. In actuality, in recent years the RUC and specialty societies have dedicated extensive resources to improving the reliability of the PE methodology. In 2007, the methodology for calculating direct PE RVUs was changed from a top-down approach to a bottom up approach, requiring a review of 100 percent of the PE inputs for all codes; this was implemented with a four-year transition that was completed in 2010. In 2010, CMS began another four-year transition to a new calculation for PE RVUs based on updated practice expense per hour calculations; this new calculation was completed in 2013.

CMS also believes that OPPS rates are more reliable than the physician PE resource inputs because they are based on auditable hospital data and are

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updated annually. We disagree with this assumption because the factors that are taken into consideration when an OPD or ASC determines costs are substantially different from the data that the RUC and CMS use to determine values under the PFS. Ambulatory payment classifications (APCs) are used for determining OPPS and ASC rates, and the Resourced-Based Relative Value Scale (RBRVS) is the basis for the PFS. These distinct payment methodologies make it inappropriate to do service-by-service comparisons. Whereas APCs are bundles that average low- and high-margin hospital services within a single APC, the RBRVS captures the relative resource costs of each individual service. Furthermore, because APCs are based on hospital cost reports it is not appropriate to use this data for PFS payment determinations, which are based on RVUs using CMS accepted PE inputs. Consequently, we believe the most appropriate source for PE RVUs and payment in the non-facility setting is the PFS.

It is also not clear how CMS would apply this policy in future years given the proposed OPPS policies to expand packaging and the development of comprehensive APCs. In addition, CMS indicates that OPPS rates are updated annually, but the significant yearly payment shifts of APC data could contribute to the existing instability in the PFS due to the SGR. In addition, this proposal would apply the cap the 2014 PFS rates based on 2013 OPPS and ASC rates, which would fail to include the most recent updates to the OPPS and ASC payment systems.

We also question whether the implementation of this policy is necessary to achieve CMS' intended goals. If the intent of this policy is to reduce services provided in the non-facility setting, CMS should make a policy decision that is directly linked to effectuating that intended goal, rather than implementing a seemingly arbitrary payment rule. Because the PFS is also used by many third party payers the PE RVUs should reflect the relative resource inputs as calculated using the CMS formula, not hard stop entries.

If CMS does proceed with the proposal, we believe that the five percent threshold for exempting codes to which this policy applies is too low. If a threshold is utilized, it should be high enough to ensure data accuracy. It should also ensure beneficiary access to a service even if utilization shifts to a different site of service. For example, there could be codes with very low volume (but above the five percent threshold, thereby subject to this new policy) for which the OPPS data are not more accurate than the current PFS inputs. Another concern with such a low threshold is that if the payment is capped at the lower of the OPPS or ASC amount, that value could be based on an extremely low ASC volume that is even less than the five percent threshold,

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potentially leading to inaccurate data. If CMS intends to use a threshold for applying this policy, we urge that it be higher, for the reasons stated above. For example, CMS maintains a policy for considering services office-based if they are on the ASC list of covered procedures and performed at least 50 percent of the time in a physician's office, so CMS does have a precedent for using considerably higher thresholds in similar policies. **Consequently, we urge CMS not to implement this proposed policy that would revise PE values by capping non-facility PE RVUs at either the OPPS or ASC facility payment levels.**

Misvalued Codes

Validating RVUs of Potentially Misvalued Codes

In the CY 2011 and CY 2012 PFS final rules, CMS finalized its proposal to develop a formal process to validate RVUs under the PFS. As a result, CMS entered into two contracts with outside entities. One of the contracts is with the Urban Institute to develop time estimates and work validation. The other contract is a two-year project with the RAND Corporation to build a validation model to predict work RVUs (wRVUs) and individual components of wRVUs, time and intensity. CMS has provided neither adequate transparency nor opportunity for public comment on these efforts. **Therefore, given that CMS has mentioned the studies in the proposed rule, we take this opportunity to provide comments and request a greater degree of transparency and opportunity for the stakeholders to whom this work directly applies to provide input and offer valuable expertise that CMS should be seeking.**

The ACS believes that it is important for the PFS to reflect accurate RVUs. However, the ACS has concerns with some of the underlying assumptions that were made from the available data used to build the validation model to predict wRVUs and to create time estimates. While CMS has provided little information on this, CMS did shed some light on this in a related *Federal Register* Information Collection Request notice. Specifically, in the *Federal Register* on February 13, 2013 requesting input on the HHS Information Collection Request, Survey of Physician Time Use Patterns under the Medicare Fee Schedule (HHS-OS-18774-60D), HHS states that "payment differentials for Evaluation and Management (E/M) services relative to procedures, rather than narrowing, have continued to widen over time."¹ The ACS believes this is both misleading as well as inappropriate for a Federal agency charged with development of a fair and unbiased payment methodology regardless of

¹"Survey of Physician Time Use Patterns under the Medicare Fee Schedule Medicare." *Federal Register* 78 (13 February 2013): 10174 -10175. Online.

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specialty of the performing provider. This is especially true in an era in which all professionals are attempting to improve the payment methodology to pay for care coordination and better quality outcomes for patients. On the contrary to the opinions expressed by CMS, there has been a massive redistribution of funding that has resulted in increases to E/M services, often at the expense of procedural services. In fact, even as Medicare inflation-adjusted payments for many physician services have steadily declined over the past two decades, the reimbursements for E/M services, as well as other services that are performed by primary care physicians have notably increased.

While the ACS fundamentally disagrees that the accuracy of the PFS should be expressed in payment differentials between specialties, we also believe the underlying premise of the studies is flawed. As a result, the ACS is concerned that the proposed studies will not accurately assess and identify potentially misvalued services or result in valid time estimates. We believe that in order to accurately identify potentially misvalued services and create valid time estimates, the contractors need to take into account that the reimbursement for E/M services, as well as other services that are performed by primary care physicians, have notably increased, thereby resulting in a narrowing of payment differentials that the HHS Information Collection Request suggests has grown. Please see Table 1, below.

Change in reimbursement for E/M services from 2009-2010				
HCPCS	DESCRIPTION	2009 AChrg	2010 AChrg	Increase 2009-2010
99214	Office/outpatient visit est	\$6,534,736,194	\$7,648,431,425	\$1,113,695,231
99204	Office/outpatient visit new	\$473,399,063	\$1,279,041,565	\$805,642,502
99213	Office/outpatient visit est	\$6,043,723,157	\$6,529,858,162	\$486,135,005
99205	Office/outpatient visit new	\$178,493,947	\$618,463,691	\$439,969,744
99203	Office/outpatient visit new	\$485,298,649	\$874,368,423	\$389,069,775
99215	Office/outpatient visit est	\$1,081,285,395	\$1,319,846,987	\$238,561,591
				\$3,473,073,848

In order to address the inaccurate assumption regarding payment differentials, the Urban Institute proposes to use operating room (OR) scheduling logs, electronic health records, and other extant sources of time as the methodology to develop time estimates. Based upon the ACS' review of similar time sources, the ACS believes this method is potentially flawed because it may be difficult to discern the intraoperative and perioperative time from OR



scheduling and OR time records. As a result, multiple areas of erroneous time data may be obtained through the use of this methodology. Furthermore, OR scheduling log data is often fraught with error because the equipment, personnel, and other resources needed to perform one procedure may be more appropriate than what is available for the procedure that is actually planned to be performed. Thus, what is scheduled to occur may not match the actual procedure(s) being performed and timed. It is also common for multiple procedures to be performed in an operating room session including central line and arterial line insertion, as well as multiple surgical procedures. As a result, allocating a specific time based on the OR scheduling log to a given scheduled operation or primary procedure performed may not yield a correct time estimate. The ACS' experience with the National Surgical Quality Improvement Program (NSQIP) database has shown that accurate time estimates for a discrete Current Procedural Terminology (CPT) code are difficult to obtain for the very reasons listed above.

The ACS also seeks additional clarity on whether the Urban Institute will attempt to measure the time taken to perform the most common and most costly CPT codes in the PFS, namely, the E/M codes. The time differences between the various levels of E/M codes are measured on the magnitude of a few minutes, but the impact of an incorrect estimation of time can have large financial impacts due to the huge numbers of E/M visits performed annually. The ACS urges CMS to ensure that the Urban Institute includes a comprehensive and validated assessment of the time taken to perform each of the E/M codes.

Drs. Robert Berenson and Peter Braun have both written extensively about the RBRVS. However, the ACS has concerns that a significant amount of their work has encouraged increasing payments for E/M services at the expense of procedural codes. In fact, on February 14, 2013, Dr. Berenson, in a testimony before the Energy and Commerce Committee of U.S. House of Representatives stated “[t]he resource-based relative value schedule that was implemented beginning 20 years ago was a definite improvement over the prior system but has not achieved its intended purpose of reorienting payment—and care—away from technical services toward primary care and what are called evaluation and management services, such as office visits. That objective has not been achieved for a few reasons.”² As a result, the ACS is concerned about the accuracy of the Urban Institute’s analysis of time discrepancies. The Omnibus Budget Reconciliation Act (OBRA) of 1989 states “the Secretary may not vary

² Robert A. Berenson, M.D., Institute Fellow, the Urban Institute. Quote from: U.S. House of Representatives. Energy and Commerce Committee. "SGR: Data, Measures and Models; Building a Future Medicare Physician Payment System." Accessed 08/28/13.

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the conversion factor or the number of relative value units for a physicians' service based on whether the physician furnishing the service is a specialist or based on the type of specialty of the physician."³ **We urge CMS to be more transparent about the process and methodologies used by the Urban Institute to ensure that unintentional payment differentials based on provider specialty are not created.**

The RAND Corporation proposes to use available data to build a validation model to predict wRVUs and the individual components of wRVUs, time and intensity. RAND proposes to design the model based on the statistical methodologies and approach used to develop the initial wRVUs and to identify potentially misvalued procedures under current RUC and CMS processes. RAND also proposes to use a representative set of CMS-provided codes to test the model and to consult with a technical expert panel on model design issues and the test results. The ACS has concerns with this methodology because it seems to be based on flawed underlying assumptions; however, CMS' lack of transparency has denied us the ability to adequately comment on the RAND analysis. As a result, the ACS is concerned that the proposed analysis will not accurately assess wRVUs, and we question the validity of the RAND analysis when there is such a significant lack of transparency surrounding the process.

The PFS uses RVUs, a conversion factor, and various adjustments to determine the reimbursement for a given service. Additionally, the relative resources that go into determining the RVUs for a given service are broken down into physician work, practice expense and malpractice expense. The work component accounts for the practitioner's effort through measures of time and intensity (i.e., cognitive effort and judgment, technical skill and physical effort, and stress due to potential patient risk) associated with providing a service. The ACS stresses the importance of relativity in valuing services across the fee schedule. If a procedure is overpriced, Medicare is wasting resources by paying more than it should and an incentive is created to provide unnecessary services. If a procedure is underpriced, it may be hard to obtain and lead to potential access problems. **We urge CMS to provide greater transparency regarding the RAND Corporation's methodology and the technical panel that will be consulted.** Additionally, we request that CMS provide the specialty societies that may be impacted by the analysis adequate opportunity for public comment.

Again, in order to bring integrity to the process of increasing the accuracy of the value of codes and physician services, it is imperative that CMS conduct

³ 42 U.S. Sec. 1395w-4(c)(6).

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these activities with transparency and base the studies on accurate assumptions. To date, this has not occurred.

Contractor Medical Director Identified Potentially Misvalued Codes

In the CY 2014 Proposed Rule, CMS states that the Medicare Contractor Medical Directors (CMDs) propose that CPT codes 47560, 47562, and 47563 are "potentially misvalued because the more extensive code has lower work RVUs than the less extensive codes."⁴

The ACS disagrees and believes that the CMDs may have overlooked the fact that 47560 (*Laparoscopy, surgical; with guided transhepatic cholangiography, without biopsy*) has a 000-day global period. Additionally, the CMDs may have looked at the CY2012 PFS where 47562 (*Laparoscopy, surgical; cholecystectomy*) and 47563 (*Laparoscopy, surgical; cholecystectomy with cholangiography*) were incorrectly ranked. For the CY2013 PFS, these codes are correctly ranked.

CPT code 47560 has a 000-day global period and as a result there is a difference in work between it and codes 47562-47563, which both have 090-day global periods. CPT code 47560 describes a diagnostic laparoscopy plus laparoscopic-guidance for percutaneous insertion of a needle or catheter into the liver parenchyma to access the biliary tree for injection of contrast and performance of trans-hepatic cholangiography. CPT code 47562 describes a diagnostic laparoscopy and surgical removal of the gallbladder. CPT code 47563 describes a diagnostic laparoscopy and surgical removal of the gallbladder with the additional work of an intraoperative cholangiography. The difference between CPT codes 47562 and 47563 is the work of the intraoperative cholangiography. This work is not the same as the total work included in code 47560. In addition, CPT codes 47562 and 47563 describe more complex surgical procedures that have a 090-day global period compared with 47560 which has a 000-day global period.

Additionally, CPT code 47563 was reviewed in October 2010. In addition, CPT code 47562, which had previously been reviewed in 1995 and 2005, was used as a stable reference service when valuing CPT code 47563. At that time the RUC recommended a wRVU of 12.11 for CPT code 47563, however, CMS reduced the value to 11.47. This resulted in a rank order anomaly for 2012 (47562 wRVU = 11.87; 47563 wRVU = 11.47).

⁴ "Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014, Proposed Rule." Federal Register 78 (19 July 2013): 43305. Online.

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In the CY 2013 PFS, CMS identified CPT codes 47562 and 47563 as potentially misvalued based on a public commenter that questioned the rank order. In January 2012, the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC) agreed that the physician work had not changed since the October 2010 review and recommended reaffirmation of the RUC's original recommendation for correctly ranked work RVUs (11.87 for 47562 and 12.11 for 47563). However, for 2013, CMS did not agree with the RUC and instead further reduced the wRVU for 47562 to correct the rank order anomaly that CMS created when it reduced the wRVU for 47563. **Although the wRVUs for 47562 and 47563 do not reflect the RUC review of survey data and RUC recommendation, their work RVUs are correctly ranked.**

Requirements for Billing “Incident To” Services

CMS proposes to revise its “incident to” regulations at §410.26 to require that the individual performing “incident to” services meet any applicable requirements to provide the services, including licensure, imposed by the state in which the services are being furnished. **The ACS supports this proposal and believes that in doing so, CMS will not only provide health and safety benefits to the Medicare patient population but will also align with the standards of the states in which services are being furnished.**

Complex Chronic Care Management Services

CMS proposes to establish a separate payment under the PFS for complex chronic care management (CCCM) and begin payment for these services in 2015. In this proposed rule CMS offers a detailed set of policies relating to CCCM services. The ACS agrees with CMS that there is a need for CCCM services and believes it is an important component to better health for individuals. Additionally, the ACS generally agrees that the care management included in many of the E/M services, such as office visits, does not adequately describe the typical non-face-to-face care management work involved for certain categories of beneficiaries. Furthermore, the ACS generally agrees that the resources required to appropriately furnish CCCM services to beneficiaries are not adequately reflected in the existing E/M codes.

However, the ACS has concerns with several of the proposed standards including CMS’ proposal to furnish CCCM services to patients with multiple (i.e., two or more) chronic conditions. **The ACS does not believe that patients with two chronic conditions represent the typical patient requiring CCCM.** In fact, CMS’ own data supports this. CMS directs readers

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to a 2012 CMS analysis of Medicare claims for patients with selected multiple chronic conditions, which states that hospitalization is an important driver of healthcare costs.⁵ The study shows that less than 10 percent of patients with zero to three chronic conditions required hospitalization in 2010. However, almost two-thirds of beneficiaries with six or more chronic conditions required hospitalization, and 16 percent of them required three or more hospitalizations during the year.⁶ Secondly, the ACS notes that a disease has various grades of severity and that work involved in caring those various grades is not uniform. For example, a patient with a mild form of diabetes or hypertension may be controlled simply with lifestyle change. Other patients with severe forms of diabetes or uncontrolled hypertension may require multiple visits and resources to control those forms of these diseases. **The ACS recommends that CMS reconsider its plan to adopt the standard as proposed and explore the appropriate additional data regarding how many chronic conditions are appropriate for CCCM.**

Another concern is with respect to the patient eligibility criteria, specifically the 15 chronic conditions identified by CMS. The ACS agrees with the American Society for Metabolic and Bariatric Surgery (ASMBS) in their separately submitted comment letter that the list of 15 chronic conditions is a good starting point for determining patient eligibility. However, this list should be expanded to include obesity, a prevalent chronic condition among Medicare beneficiaries with serious deleterious effects. On June 18, 2013, the American Medical Association (AMA) officially recognized obesity as a disease. A statement from AMA board member Patrice Harris, MD, notes the complex nature of the condition and its common comorbidities, “Recognizing obesity as a disease will help change the way the medical community tackles this complex issue that affects approximately one in three Americans. The AMA is committed to improving health outcomes and is working to reduce the incidence of cardiovascular disease and type 2 diabetes, which are often linked to obesity.”⁷

CMS discusses 15 chronic conditions to be eligible for the proposed complex care management payment. We note that 13 of these 15 conditions (high blood

⁵ Medicare claims for patients with selected multiple chronic conditions, available at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/Downloads/2012Chartbook.pdf>.

⁶ Medicare claims for patients with selected multiple chronic conditions, available at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/Downloads/2012Chartbook.pdf>.

⁷ American Medical Association, June 18, 2013. Press Release: AMA Adopts New Policies on Second Day of Voting at Annual Meeting. Accessed on July 19, 2013 at <http://www.ama-assn.org/ama/pub/news/news/2013/2013-06-18-new-ama-policies-annual-meeting.page>.



pressure, high cholesterol, ischemic heart disease, arthritis, diabetes, heart failure, chronic kidney disease, depression, COPD, atrial fibrillation, certain cancers, asthma, and stroke) are commonly associated with obesity and/or are exacerbated by obesity.^{8,9,10,11,12} While some obese beneficiaries may have two or more of these 15 conditions in addition to obesity, if CMS does not add obesity to the list of included conditions, beneficiaries who have obesity and one of the other chronic conditions on the list (e.g., heart disease or diabetes) would be excluded from complex care management services coverage. This creates a perverse incentive, since care management could potentially prevent these beneficiaries from developing additional comorbidities commonly associated with obesity.

Furthermore, obesity clearly meets the criteria CMS outlines in the proposed rule as the rationale for selecting the 15 chronic conditions eligible for the complex chronic care management payments. Specifically, obesity (1) is highly prevalent among the Medicare population; (2) is chronic; i.e., typically lasts for more than 12 months; (3) poses increased risk for death, acute exacerbation/decompensation, or functional decline; (4) results in increased use of health care services; and (5) successful care management can improve outcomes/reduce costs. **The ACS supports the ASMBS' recommendation that CMS add obesity to the list of chronic conditions that make a patient eligible for CCCM services.**

The ACS is also concerned with the appropriate utilization of CCCM services. These services are meant to improve coordination of healthcare delivery and lower healthcare expenditures. The ACS believes the CCCM, if properly established and measured, has the potential to reduce costs by reducing emergency department and inpatient hospital utilization. However, the ACS is concerned that there is a lack of auditable guidance regarding hospital admissions, which is a driver of healthcare costs, for patients receiving CCCM. To ensure that the opportunity to observe the effectiveness of these new codes

⁸ NHLBI, Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults, NIH Publication No. 98-4083, September 1998.

⁹ Beuther DA, Sutherland ER. Overweight, Obesity, and Incident Asthma: A Meta-analysis of Prospective Epidemiologic Studies. *Am J Respir Crit Care Med.* 2007;175:661–6.

¹⁰ Dolan CM, Fraher KE, Bleecker ER, et al. Design and baseline characteristics of the epidemiology and natural history of asthma: Outcomes and Treatment Regimens (TENOR) study: a large cohort of patients with severe or difficult-to-treat asthma. *Ann Allergy Asthma Immunol.* 2004;92:32–9.

¹¹ Kopple JD, Feroze U.J. The effect of obesity on chronic kidney disease. *Ren Nutr.* 2011 Jan;21(1):66-71.

¹² Wanahita N, Messerli FH et. al. Atrial Fibrillation and Obesity -- Results of a Meta-Analysis. *Am Heart J.* 2008;155(2):310-315.

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exists, there needs to be a way to link the physician work to quality measures and to have an identifier that enables one to identify that the CCCM services are being appropriately utilized and that the policies are effective. **As such, the ACS recommends that CMS develop a mechanism to monitor hospital admissions during the 90-day chronic care management period to determine if this effort positively impacts beneficiary outcomes and decreases the burden on the healthcare system. To do this, physicians would need to report CCCM care at the beginning and end of the 90-day care period.** Otherwise, there will be no auditable method to determine hospital admission rates for patients receiving CCCM services. This may require a “start” and a “stop” modifier to the new G-codes, where GXXX1- or GXXX2-X1 (start modifier), is reported on the first day of the 90-day care period and GXXX1- or GXXX2-X2 (stop modifier), is reported 90 days later for payment. These “tracking” modifiers are similar to CMS’ modifier AI (physician of record) that is appended to the initial hospital care visit codes to designate the admitting physician. This will provide valuable information over time identifying whether the care that is supposed to be delivered in association with these codes is achieving the intended results.

CMS states that this proposal is a part of its broader multi-year strategy to appropriately recognize and value primary care and care management services. Furthermore, CMS states that one of the primary reasons for the proposed 2015 implementation date is to provide sufficient time to develop and obtain public input on the standards necessary to demonstrate the capability to provide these services. As such, the ACS is concerned that CMS is proposing to create policies and standards that have not been refined to appropriately describe the work of managing the care of chronically ill beneficiaries. **We urge CMS not to finalize the proposed policies and standards in the CY 2014 Final Rule to ensure that sufficient exploration of potential refinements are done and the standards and policies that are set enable physicians to accomplish the appropriate care for beneficiaries requiring these services.** Given that CMS does not contemplate use of the codes until 2015, this recommendation to not finalize any provisions of this proposal should be feasible.

OTHER PROVISIONS OF THE PROPOSED RULE

Ultrasound Screening for Abdominal Aortic Aneurysms

CMS proposes to modify the Medicare coverage rules for ultrasound screening for abdominal aortic aneurysms (AAA) to eliminate the current one-year time limit with respect to the referral for this service. Under the proposal, eligible Medicare beneficiaries would not be required to receive a referral as part of the

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Initial Preventive Physical Examination to be screened one time for AAA. The Society for Vascular Surgery indicates that AAA screening is currently underutilized and this proposal would allow for expanded access to this important preventive service. **As such, we strongly support CMS' proposal to modify the coverage rules for ultrasound screening of AAA.**

Colorectal Cancer Screening: Modifications to Coverage of Screening Fecal Occult Blood Tests

CMS proposes to revise Medicare coverage rules to allow physician assistants, nurse practitioners, or clinical nurse specialists to furnish written orders for screening Fecal Occult Blood Tests (FOBT). Currently, only the attending physician may furnish such orders. **We support this proposal and agree with CMS that this modification would allow for expanded coverage and access to screening FOBT.** We also believe that the practitioner permitted to order a screening FOBT should not be limited to the attending practitioner (i.e. the practitioner who is fully knowledgeable about the beneficiary's medical condition and who would be responsible for using the results of any examination performed in the overall management of the beneficiary's medical problem). If CMS' goal is to expand access to this important screen for colon cancer, non-attending practitioners should also be allowed to order the test as well.

Physician Compare Web site

Public Reporting of Physician Performance Data

Since the initial launch of the Physician Compare Web site in 2010, CMS has made significant efforts to redesign and improve the Web site. In 2013, CMS launched the redesigned Physician Compare Web site that included a complete overhaul of the Web site's underlying database and added a new search feature. CMS improved the accuracy of the Web site's underlying data source, the Provider Enrollment, Chain, and Ownership System (PECOS), by using Medicare claims data to verify physicians' information. CMS also improved the search function related to how physicians and specialties are listed by adding the "Intelligent Search" function. This function allows users the ability to search for a Medicare physician by defining a location and by entering a medical specialty, health care professional or group name, medical condition, body part, or organ system. The Web site currently allows users to view certain types of information about a provider including a provider's name, primary and secondary specialty, practice locations, group affiliations, hospital

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affiliations, Medicare Assignment status, education, languages spoken, and board certification information.

Although the ACS appreciates these changes, we believe that Physician Compare needs additional improvements to ensure that both the search function and underlying demographics of the data are accurate. For example, we conducted a search for general surgeons in zip code 60601 and found 13 primary care physicians listed as "related" to general surgery. These providers were listed in addition to 124 general surgeons. We do not know how the 13 primary care physicians came to be related to general surgery; they are all from two small internal medicine groups. These 13 primary care physicians also are a very small minority of the vast number of primary care physicians in the 60601 zip code. This type of information is misleading and not helpful to patients who may use the site to compare general surgeons.

Additionally, users can also view which quality programs an eligible professional (EP) successfully reported. CMS indicates this by placing a check mark next to the program name on the profile page of each individual EP. Users can view whether an EP satisfactorily reported under the Physician Quality Reporting System (PQRS) and the Medicare Electronic Health Record (EHR) Incentive Program, as well as those who were successful electronic prescribers under the Medicare Electronic Prescribing (eRx) Incentive Program. CMS also plans to indicate with a check mark whether an EP reported on the PQRS Cardiovascular Prevention measures group in support of the Million Hearts Initiative as well as those who earned a PQRS-related Maintenance of Certification (MOC) additional incentive. ACS supports CMS' decision to only indicate successful participation information on the EP's profile page so as not to negatively reflect on those who were unsuccessful or could not participate. **Because of the potential for information to be misconstrued, we encourage CMS to continue its practice of only posting successful participation for other quality reporting program information they would like to post on the profile page of EPs and groups in the future.**

Future Development of Physician Compare

CMS will continue to expand Physician Compare by incorporating quality measures from a variety of sources. For example, CMS proposes to publicly report, no earlier than 2015, on Physician Compare performance for certain measures that groups report via registries and EHRs in the 2014 group practice reporting option (GPRO). In addition, CMS will post patient experience of care survey measures from the Clinician and Group Consumer Assessment of

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Healthcare Providers and Systems (CG-CAHPS) survey in 2014. CG-CAHPS data will be publicly reported for those participating in the PQRS GPRO Web-interface (which applies to both groups of 100 or more as well as those participating in the Medicare Shared Savings Program as Accountable Care Organizations). CMS will continue to collect patient experience of care data for these groups in 2014 for public reporting in 2015, as well as continue to administer and fund the survey for these groups. In addition to publicly reporting patient experience of care measures for these specific groups, CMS also proposes to publicly report on patient experience of care measures for groups of any size who voluntarily report CG-CAHPS data through the newly proposed PQRS certified survey vendor option. Should this new PQRS reporting option be finalized, groups of 25-99 will be allowed to report on CG-CAHPS measures through a certified survey vendor, but will be required to fund the survey on their own.

ACS strongly urges CMS to include the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey (S-CAHPS) as an optional patient experience of care measure for the certified survey vendor reporting option. S-CAHPS more closely assesses the patient experience during an episode of surgical care compared to CG-CAHPS, and therefore inclusion of S-CAHPS will allow surgeons to report on a measure that more accurately reflects the care they deliver. Additionally, if CMS begins to publicly report patient experience of care measures on Physician Compare, patients in need of surgery should be able to view information relevant to the care they seek. Furthermore, if CMS permits groups of 25-99 to report on CG-CAHPS through a certified survey vendor, groups should have the option to select S-CAHPS if they will be required to fund survey administration. The fact that CMS is not administering all CAHPS surveys in the future removes one of the hurdles to including the S-CAHPS.

In addition, CMS seeks comments on expanding public reporting to possibly include specialty-society approved and vetted measures on Physician Compare. We are appreciative of CMS' willingness to accept measures from approved and vetted specialty societies. However, we seek clarification on what exactly this would look like, what types of measures CMS is conceptualizing, and whether these specialty-developed measures would replace measures that CMS is considering, or if they would be in addition to what the agency is considering.

Finally, ACS recommends that CMS continue to collaborate with specialty societies, possibly via town hall meetings and other mechanisms, to determine what physician information is helpful for a patient. We believe that CMS

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should focus on communicating validated and meaningful information to patients to help them make an informed decision rather than overwhelming them with an abundance of unnecessary information.

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

Proposed Changes to the Criterion for Satisfactory Reporting of Individual Quality Measures via Claims for Individual EPs for the 2014 PQRS Incentive

In the CY 2013 PFS final rule,¹³ CMS finalized the following reporting criterion for reporting individual quality measures via claims for individual EPs: for the 12-month reporting period for the 2014 PQRS incentive, report at least three measures, or if less than three measures apply to an EP, report one to two measures (which would be subject to the Measures Applicability Validation (MAV) process), and report each measure for at least 50 percent of the EP's Medicare Part B Fee For Service (FFS) patients seen during the reporting period to which the measure applies. Measures with a zero percent performance rate would not be counted.

However, in the CY 2014 PFS proposed rule, CMS proposes the following reporting requirement for individual measures via claims for individual EPs to earn the 2014 PQRS incentive: for the 12-month reporting period for the 2014 PQRS incentive, report at least nine measures, covering at least three of the National Quality Strategy (NQS) domains, or, if less than nine measures apply to the EP, report one to eight measures (subject to the MAV), and report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a zero percent performance rate would not be counted.

ACS believes that the increase from reporting on at least three measures to reporting a minimum of nine measures is too high, especially since there are very limited measures for the claims-based reporting method. **Instead of increasing the minimum reporting requirement to nine measures, ACS believes that CMS should consider making the requirement such that EPs report on a minimum of three NQS domains.** This would require EPs to report on a minimum of three measures and not be obligated to report on at

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¹³ Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013, 77 Fed. Reg. 68,891 (16 November 2012).



least nine measures. We believe that there should be more emphasis placed on reporting measures within NQS domains rather than the total number of measures reported.

CMS proposes to decrease the number of patients for which an EP must report for each measure from 80 percent to 50 percent of an EP's applicable patients in order to align the percentage thresholds for registry reporting with the percentage threshold established for reporting via the claims-based reporting mechanism. ACS supports lowering the threshold from 80 to 50 percent.

*Proposed Changes to the Criterion for Satisfactory Reporting of **Individual Quality Measures** via **Registry** for **Individual EPs** for the **2014 PQRS Incentive***

In the CY 2013 PFS final rule, CMS finalized the following reporting criterion for reporting individual quality measures via a registry for individual EPs: for the 12-month reporting period for the 2014 PQRS incentive, report at least three measures and report each measure for at least 80 percent of the EP's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a zero percent performance rate would not be counted.

However, in the CY 2014 PFS proposed rule, CMS proposes the following reporting requirement for individual measures via a registry for individual EPs to earn the 2014 PQRS incentive: for the 12-month reporting period for the 2014 PQRS incentive, report at least nine measures, covering at least three of the NQS domains and report each measure for at least 50 percent of the EP's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a zero percent performance rate would not be counted.

CMS believes that collecting data on nine measures rather than three measures will be valuable as it will provide a better picture of an EP's overall quality of care. CMS also notes that their proposal to increase the number of measures reported via claims and registry will align with the established reporting option for the EHR-based reporting mechanism which requires the reporting of nine measures covering three of the NQS domains.

As previously noted, ACS believes that the increase from reporting on at least three measures to reporting a minimum of nine measures is too high. Instead of increasing the minimum reporting requirement to nine measures, ACS believes that CMS should consider making the

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requirement such that EPs report on a minimum of three NQS domains. This would require EPs to report on a minimum of three measures and not be obligated to report on at least nine measures. We believe that there should be more emphasis placed on reporting measures within NQS domains rather than the total number of measures reported.

CMS proposes to decrease the number of patients for which an EP must report for each measure from 80 percent to 50 percent of an EP's applicable patients in order to align the percentage thresholds for registry reporting with the percentage threshold established for reporting via the claims-based reporting mechanism. **ACS supports lowering the threshold from 80 to 50 percent.**

*Proposed Changes to the Criterion for Satisfactory Reporting of **Measures Groups** via **Claims** for **Individual Eligible Professionals** for the **2014 PQRS Incentive***

In the CY 2013 PFS Schedule final rule, CMS finalized the following criterion for individual EPs to report measures groups via claims: report at least one measures group and report each measures group for at least 20 Medicare Part B FFS patients. Measures groups containing a measure with a zero percent performance rate will not be counted.

CMS notes that this option is not widely used, citing a low number of participants—only 4,472 EPs—in the 2011 PQRS and eRx Experience Report.¹⁴ As such, they are proposing to eliminate this reporting option for 2014. Should this option be eliminated for 2014 PQRS, the only way an EP would be able to report a PQRS measures group would be through a registry.

ACS does not support this elimination of measures group via claims for individual EPs. We believe that in order to maximize the number of participants in the program, there should be a wide range of reporting options. If the measures group option is only available through a registry, EPs who want to use this mechanism will either be forced to participate via a registry and possibly incur an additional financial burden or will no longer be able to participate if a particular registry does not support the measures groups an EP would like to report on. In addition, if CMS finalizes the proposals regarding the number of measures that must be reported, for those EPs who must report via claims, the removal of this option would force them to report on nine measures. The EP might not have nine measures on which he or she

¹⁴ Centers for Medicare and Medicaid Services, Appendix, *2011 Reporting Experience Including Trends (2008-2012): Physician Quality Reporting System and Electronic Prescribing (eRx) Incentive program* (April 9, 2013), 39.

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can report. The other option would be for the EP to be subject to the MAV process, but that increases the administrative burden for both the EP and CMS.

Proposed Criteria for Satisfactory Reporting for the 2016 PQRS Payment Adjustment for Individual Eligible Professionals using the Claims and Registry Reporting Mechanisms

CMS materials given at a briefing with the American Medical Association on August 1, 2013 noted an additional proposed change to the criteria to avoid the 2016 PQRS payment adjustment that was not mentioned in the CY 2014 PFS Proposed Rule. This option would be available to individual EPs who report individual measures via claims during the 12-month reporting period between January 1-December 31, 2014: report on at least three measures, or if less than three measures apply to the EP, report on one to two measures and report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period for which the measure applies. Measures with a zero percent performance rate would not be counted. This option would allow EPs to avoid the 2016 payment adjustment, but not earn the 2014 PQRS payment incentive. **We would request that CMS clarify this option for avoiding the 2016 penalty in a correction notice or in the CY 2014 PFS Final Rule.**

Proposed Criteria for Satisfactory Reporting for the 2014 PQRS Incentive for Group Practices in the GPRO

GPRO web interface reporting option

In the CY 2013 PFS Schedule final rule, CMS finalized the following criterion for the satisfactory reporting of PQRS quality measures to earn the 2014 PQRS incentive via the GPRO web interface for group practices comprised of 25-99 EPs: report on all measures included in the web interface; and populate data fields for the first 218 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 218, then report on 100 percent of assigned beneficiaries.

CMS proposes to eliminate the GPRO web interface reporting option for groups of 25-99 EPs. As a result, group practices comprised of 25-99 EPs would need to report PQRS quality measures using either the registry or EHR-based reporting mechanisms. While we believe the GPRO web interface is of limited use to specialists, we do think CMS should consider maintaining reporting flexibility to encourage participation in the PQRS program.

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Registry-based reporting option

In the CY 2013 PFS Schedule Final Rule, CMS finalized the following criterion for the satisfactory reporting of PQRS quality measures to earn the 2014 PQRS incentive via GPRO using the registry-based reporting mechanism, for group practices comprised of two or more EPs: report at least three measures, and report each measure for at least 80 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a zero percent performance rate will not be counted.

However, in the 2014 PFS proposed rule, CMS proposes the following modified criteria for the satisfactory reporting of individual quality measures under the GPRO for the registry-based reporting mechanism for the 2014 PQRS incentive: report at least nine measures covering at least three of the NQS domains and report each measure for at least 50 percent of the group practice's applicable seen during the reporting period to which the measure applies. Measures with a zero percent performance rate will not be counted.

To reiterate, ACS believes that the increase from reporting on at least three measures to reporting a minimum of nine measures is too high. Instead of increasing the minimum reporting requirement to nine measures, ACS believes that CMS should consider making the requirement such that EPs report on a minimum of three NQS domains. This would require EPs to report on a minimum of three measures and not be obligated to report on at least nine measures. We believe that there should be more emphasis placed on reporting measures within NQS domains rather than the total number of measures reported.

Certified survey vendor reporting option

In addition to the previous reporting options for GPROs, CMS is proposing a new reporting option for GPROs consisting of 25 or more EPs for the 2014 PQRS incentive: for the 12-month reporting period for the 2014 PQRS incentive, report all CAHPS survey measures via a certified vendor, and report at least six measures covering at least two of the NQS domains using the qualified registry, direct EHR product, EHR data submission vendor, or GPRO web interface reporting mechanisms.

ACS believes that this reporting option should be inclusive of other comparable surveys including S-CAHPS survey. CAHPS has been tested by the same standards as the CG-CAHPS, follows the same collection

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mechanism as the CG-CAHPS and is just as accurate. The S-CAHPS expands on the CG-CAHPS by focusing on aspects of surgical quality that are important from the patient's perspective and for which the patient is the best source of information. The survey asks patients to provide feedback on surgical care, surgeons, their staff, and anesthesia care. It assesses patients' experiences with surgical care in both the inpatient and outpatient settings by asking respondents about their experience before, during and after surgery. Additionally, ACS believes that this option should also be available to groups of two or more EPs in order to maximize participating in the PQRS program.

*Proposed **Individual PQRS Measures** and **Measures within Measures Groups** Available for Reporting for **2014** and Beyond*

S-CAHPS

ACS strongly urges the inclusion of the S-CAHPS as an individual PQRS measure. If S-CAHPS is included in PQRS for individual reporting, it will be voluntary, which would allow physicians to select the patient experience of care survey that is most appropriate for their patient population. Physicians could then choose from the CG-CAHPS, Hospital CAHPS or S-CAHPS depending on the care they deliver.

S-CAHPS has been tested by the same standards as the CG-CAHPS, follows the same collection mechanism as the CG-CAHPS and is just as accurate. The S-CAHPS expands on the CG-CAHPS by focusing on aspects of surgical quality that are important from the patient's perspective and for which the patient is the best source of information. The survey asks patients to provide feedback on surgical care, surgeons, their staff, and anesthesia care. It assesses patients' experiences with surgical care in both the inpatient and outpatient settings by asking respondents about their experience before, during, and after surgery.

The ACS, in partnership with other surgical and anesthesia organizations and the Agency for Healthcare Research and Quality's (AHRQ) CAHPS Consortium, developed the survey to assess surgical patients' experiences before, during, and after surgical procedures to adequately identify opportunities to improve quality of care, surgical outcomes, public reporting, and patient experience. The S-CAHPS survey was developed using the same methodology and scientific rigor applied when developing all CAHPS surveys. Nine surgical specialties participated in the main field test conducted during the development of the survey, which included colon and rectal, ophthalmology, general surgery, orthopaedic, plastic surgery, otolaryngology,

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thoracic, urology, and vascular. The S-CAHPS Technical Advisory Panel (TAP) included 21 members from various specialty societies. The S-CAHPS is the only National Quality Forum (NQF)-endorsed measure designed to assess surgical quality from the patient's perspective. NQF endorsement confirms that the survey meets the "gold standard" in quality measurement. The NQF's Measure Application Partnership (MAP) "supported" S-CAHPS inclusion in PQRS.¹⁵

General Surgery Measures, Gastrointestinal Surgery Measures, and, Patient-Specific Risk Calculator

CMS proposes new measures to be included in the PQRS measure set for 2014 and beyond, listed in Table 29 of the proposed rule, which also includes the reporting mechanism(s) for each measure listed in the Table. We would like to highlight that the measures included in the General Surgery measures group and Gastrointestinal measures group are also included in the individual PQRS measures table. However, they are listed as only being reportable via Measures Group and therefore it is unclear if measures within measures group list can be reported individually. **Because CMS is proposing to increase the requirement for individual measures from three measures to nine measures, we strongly urge CMS to make these measures available for both individual measure reporting and measures group reporting.** The measures are as follows:

- Ventral Hernia, Appendectomy, AV Fistula, Cholecystectomy, Thyroidectomy, Mastectomy +/- Lymphadenectomy or SLNB, Partial Mastectomy or Breast Biopsy/Lumpectomy +/- Lymphadenectomy or SLNB: Iatrogenic Injury to Adjacent Organ/Structure
- Ventral Hernia, Appendectomy, AV Fistula, Cholecystectomy, Thyroidectomy, Mastectomy +/- Lymphadenectomy or SLNB, Partial Mastectomy or Breast Biopsy/Lumpectomy +/- Lymphadenectomy or SLNB: Unplanned Reoperation within the 30 Day Postoperative Period
- Ventral Hernia, Appendectomy, AV Fistula, Cholecystectomy, Thyroidectomy, Mastectomy +/- Lymphadenectomy or SLNB, Partial Mastectomy or Breast Biopsy/Lumpectomy +/- Lymphadenectomy or SLNB: Unplanned Hospital Readmission within 30 Days of Principal Procedure
- Ventral Hernia, Appendectomy, AV Fistula, Cholecystectomy, Thyroidectomy, Mastectomy +/- Lymphadenectomy or SLNB, Partial

¹⁵ National Quality Forum. MAP Pre-Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS: 53. Available at: http://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx.

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Mastectomy or Breast Biopsy/Lumpectomy +/- Lymphadenectomy or SLNB: Surgical Site Infection (SSI)

- Bariatric Laparoscopic or Open Roux-en Y Gastric Bypass, Bariatric Sleeve Gastrectomy, and Colectomy: Iatrogenic Injury to Adjacent Organ/Structure
- Bariatric Laparoscopic or Open Roux-en Y Gastric Bypass, Bariatric Sleeve Gastrectomy, and Colectomy: Anastomotic Leak Intervention
- Bariatric Laparoscopic or Open Roux-en Y Gastric Bypass, Bariatric Sleeve Gastrectomy, and Colectomy: Unplanned Reoperation within the 30 Day Postoperative Period
- Bariatric Laparoscopic or Open Roux-en Y Gastric Bypass, Bariatric Sleeve Gastrectomy, and Colectomy: Unplanned Hospital Readmission within 30 Days of Principal Procedure
- Bariatric Laparoscopic or Open Roux-en Y Gastric Bypass, Bariatric Sleeve Gastrectomy, and Colectomy: Surgical Site Infection (SSI)

Patient-Specific Risk Calculator. Additionally, the ACS strongly urges CMS to include the measure entitled *“Patient-Centered Surgical Risk Assessment and Communication: The Percent of Patients who Underwent Non-Emergency Major Surgery Who Received Preoperative Risk Assessment for Procedure-Specific Postoperative Complications using a Data-Based, Patient-Specific Risk Calculator, and who also Received a Personal Discussion of Risks with the Surgeon”* as an individual measure. This measure is currently listed as registry-based reporting. This is a critically important measure that is at the very heart of shared decision making and informed consent for surgical patients and therefore should be available as an option across PQRS programs.

As the measure steward of the patient specific risk calculator, we have had many questions from other surgical specialties regarding which procedures are included in the specifications. Therefore, we would like to clarify that this measure is not intended to be, nor do we believe CMS has structured it as, limited to risk calculators developed by ACS. PQRS participants should choose a risk calculator that represents their patient population, but the risk calculator chosen should be procedure-specific, patient-specific, and data- or population-based.

The ACS Surgical Risk Calculator is based on a validated, risk-adjusted statistical model predicting 30-day postoperative complications for the procedure that the patient is to undergo. Risk calculations are based on preoperative patient-specific data, and include the following groups of variables: patient demographic characteristics (e.g., age, gender, race); relevant

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lifestyle and clinical risk factors (e.g., smoking status, American Society of Anesthesiologists class, body mass index); patient comorbidities (e.g., diabetes; neurologic event/disease; disseminated cancer); procedure type; and procedure indication. Postoperative complications include: 30-day risk-adjusted mortality and 30-day risk-adjusted overall morbidity (superficial surgical site infection, deep incisional surgical site infection, wound dehiscence, pneumonia, deep venous thrombosis; pneumonia; renal failure; urinary tract infection; prolonged ventilator dependence; bleeding complications; sepsis; and pulmonary embolism).

Examples of risk calculators we believe are acceptable for this measure include, but are not limited to: the ACS NSQIP pancreatectomy risk calculator, ACS NSQIP colorectal surgery risk calculator, the bariatric surgery risk calculator based on ACS NSQIP data, ACS NSQIP risk calculator that can be used for nearly any operation in general surgery, vascular surgery, orthopedics, gynecology, otolaryngology, urology, plastic surgery, thoracic surgery, and neurosurgery (<http://riskcalculator.facs.org>), and other risk calculators from Society of Thoracic Surgery and the American Society of Breast Surgeons.

Proposed PQRS Measures Groups

For CY 2014, CMS proposes to increase the minimum amount of measures that may be included in a PQRS measures group from four measures to six measures. Prior to this proposal CMS has defined a measures group as “a subset of four or more Physician Quality Reporting System measures that have a particular clinical condition or focus in common. The denominator definition and coding of the measures group identifies the condition or focus that is shared across the measures within a particular measure group.”¹⁶ The rationale that CMS provides for this change is that they believe it is appropriate to increase the number of measures to better align with the proposal to increase the number of measures from three measures to nine measures for individual EPs. CMS notes that increasing the number of measures in a group to six measures is reasonable because the EP would be required to report on all of the measures in a group as opposed to any nine PQRS measures of the EPs liking. To meet this new proposed requirement, CMS has added additional measures to groups that previously contained less than six measures.

ACS agrees that EPs should provide a broad representation of the care they provide. **However, we believe that requiring measures groups to have a**

¹⁶ “Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014, Proposed Rule.” Federal Register 78 (19 July 2013): 43448. Online.

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minimum of six measures is arbitrary. Instead, we think that is more meaningful to cover three NQS domains which will result in broader strides towards achieving the NQS. To this end, we urge CMS to continue to define a measures group as a subset of a minimum of four measures, covering three NQS domains.

CMS proposes two new surgical measures groups and one modified measures group for CY 2014 and beyond. The newly proposed measures groups are General Surgery and Gastrointestinal Surgery, and the modified measures group is the Perioperative Care Measure Group. We thank CMS for including two new options for surgeons.

CMS proposes a new Cataracts Measures Group that includes the measure entitled *Patient- Centered Surgical Risk Assessment and Communication: The Percent of Patients who Underwent Non-Emergency Major Surgery Who Received Preoperative Risk Assessment for Procedure-Specific Postoperative Complications using a Data-Based, Patient-Specific Risk Calculator, and who also Received a Personal Discussion of Risks with the Surgeon*. Although this is a critically important measure that is at the very heart of shared decision making and informed consent for surgical patients, the ACS Surgical Risk Calculator does not capture cataract procedures, and we are not aware of any other risk calculators that do. Because of the requirement that physicians be able to report on every measure within a measures group, the risk calculator measure should be removed from the proposed Cataracts Measure Group. Based on the current known availability of risk calculators, **this measure is appropriate for the General Surgery Measures Group, Gastrointestinal Measures Group, and the Perioperative Care Measures Group and therefore should be maintained in these groups but deleted from the Cataracts Measures Group.**

Proposals Related to Satisfactory Participation in a Qualified Clinical Data Registry by Individual Eligible Professionals

The ACS is interested in improving the capability and utility of clinical quality measures currently being captured by ACS and other entities with clinical data registries. We believe measures from specialty registries can be more relevant, clinically appropriate, and actionable for surgeons when compared to the measures currently available as reporting options through PQRS.

Congressional Intent. In December, 2012, Congress intended to empower CMS to support clinical registries with the passage of section 601(b), Advancement of Clinical Data Registries to Improve the Quality of Health

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Care, of the American Taxpayer Relief Act of 2012. This provision authorizes participation in a clinical data registry as an option for individual EPs to meet PQRS reporting requirements. In response to this provision, beginning in 2014, CMS proposes the Qualified Clinical Data Registry (QCDR) reporting as its response to the legislative mandate. CMS defines a QCDR as “a CMS-approved entity that collects medical and/or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care furnished to patient.”¹⁷ However, ACS believes QCDRs, as articulated by CMS in the Proposed Rule, fail to capitalize on the opportunity to streamline the value of registries with CMS’ need for quality information and does not align with Congressional intent.

In April 2013, CMS solicited a Request for Information (RFI) on the Use of Clinical Quality Measures (CQMs) Reported under the Physician Quality Reporting System (PQRS), the Electronic Health Record (EHR) Incentive Program, and Other Reporting Programs. In response the RFI, ACS provided the following response:

The provisions in the Tax Payer Relief Act which relate to PQRS and the EHR Incentive Program were put into law because of the inflexibility and low participation rates of the current program requirements. **Therefore, we urge CMS to NOT replicate the reporting structure of these programs in their rulemaking process.** Though we agree that CMS will need to set parameters to ensure that the information being collected is meaningful, CMS must recognize the clear weaknesses in the current programs and ensure that there are additional options which are user-friendly and flexible in regard quality measurement data collection. [Emphasis added]¹⁸

Unfortunately, under the proposed rule, CMS has replicated the reporting structure of the current PQRS program. **To this end, we urge CMS to reconsider the comments it received in response to the RFI mentioned above, and design a QCDR program that is consistent with Congressional**

¹⁷ “Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014, Proposed Rule.” Federal Register 78 (19 July 2013). 43361. Online.

¹⁸ Comment of the American College of Surgeons comment on the Request for Information (RFI) on the Use of Clinical Quality Measures (CQMs) Reported under the Physician Quality Reporting System (PQRS), the Electronic Health Record (EHR) Incentive Program, and Other Reporting Programs (April 8, 2013).

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intent. We encourage CMS to reshape the QCDR program to address these challenges.

General Concerns. We would like specifically to highlight two sections of the American Taxpayer Relief Act of 2012: The American Taxpayer Relief Act of 2012 includes a provision that:

The Secretary shall, “establish a process to determine whether or not an entity meets the requirements” of the program. Such a process may involve one or both of the following:

- I. A determination by the Secretary.*
- II. A designation by the Secretary of one or more independent organizations to make such determination.”¹⁹*

Under this provision, CMS has the opportunity to deem an entity capable of evaluating clinical registries to ensure they meet the standards of the QCDR program. **We seek clarification on who will be given the authority to determine whether an entity fits this definition in order to be deemed a QCDR. We seek further clarification on this process from CMS as soon as possible.** ACS assumes that there will be additional associated rulemaking on this process. If CMS is not planning on an associated rulemaking process, we strongly encourage them to do so.

In addition, the ATRA states:

The registry must provide the Secretary with “such information, at such times, and in such a manner, as the Secretary determines necessary to carry out this subsection” (referring to the section titled “Advancement of Clinical Data Registries to Improve the Quality of Health Care.”)²⁰

Although CMS has a broader mandate to improve clinical quality through the collection of data and imposition of quality measures, the statute establishing the QCDR program does not require that CMS collect raw data from clinical registries. Rather, the statute only requires that CMS collect information on whether a physician is satisfactorily reporting to the registry. We do

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¹⁹ “Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014, Proposed Rule.” Federal Register 78 (19 July 2013). 43364. Online.

²⁰ “Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014, Proposed Rule.” Federal Register 78 (19 July 2013): 43361. Online.



understand that as part of the broader mandate to improve clinical quality CMS is mandated to calculate the value-based payment modifier, and therefore must have access to data required for those calculations. **To this end, we oppose the submission of patient-identifiable and/or raw data, and support the submission of performance rates calculated and submitted by the QCDR.** We also seek clarification on what data is absolutely necessary for CMS to collect for purposes of calculating the value-based payment modifier.

In addition, in creating the QCDR data-sharing requirements, we believe that CMS must consider feasibility. The objectives of clinical registries often expand beyond quality measure reporting as contemplated by CMS in this Proposed Rule. The primary purpose of many registries is to track quality of care for targeted medical or surgical procedures, to provide medical groups and hospitals with invaluable data for analyzing and reporting their performance—including the generation of risk-adjusted national and local benchmarks—and to ultimately improve patient outcomes. As a result, data collected is expansive and therefore extremely expensive and burdensome to sort and prepare for use. Furthermore, we do not think that CMS should be granted access the proprietary information collected by registries, or access to information that registries and medical boards collaborate on for purposes of maintenance of certification (MOC). We believe that a robust validation strategy and transparent auditing guidance will be sufficient in lieu of submitting patient-level data with identifiers and/or raw data.

Proposed Requirements for a QCDR

Despite our concerns regarding CMS' interpretation of The American Taxpayer Relief Act of 2012, ACS believes that the proposed requirements for an entity to be considered a QCDR will be difficult to meet. As currently outlined, these requirements will likely limit the ability for clinical registries to participate as a QCDR, and thus continue to limit participation in PQRS. These concerns and additional comments are outlined below.

“In Existence.” CMS proposes that a QCDR be in existence as of January 1 the year prior to the year for which the entity seeks to become a QCDR. We seek clarity on what defines being “in existence” given that few, if any, existing registries will be configured exactly as contemplated in the proposed rule. **To this end, while we believe there could be multiple ways to assess whether a registry was previously “in existence,” we recommend the following options: 1) registries that have been in existence as a qualified PQRS registry for one year would also be deemed as having been in**

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existence; and/or 2) clinical registries that have demonstrated some combination of the following characteristics:

1. pursue quality & safety across a population as its primary mission;
2. demonstrate improvement in care, including published, peer-reviewed evidence for clinical improvement in care;
3. focus on outcomes or processes that are closely linked to outcomes;
4. have the ability to compare care delivered across multiple providers or delivery systems (*i.e.* not a single report from an electronic health record);
5. allow for accepted risk adjustment or case-mix adjustment. In certain instances, a composite/group of measures that target the continuum of care would be acceptable, and might include a collection of structure, process, and outcome measures;
6. focus on patients with high impact, high volume, (unwarranted) variation, addressing access to care and disparities in care at the population level in order to evaluate/improve health care. The provider focus of the registry should be sufficiently flexible to allow for instances where team-based quality (*i.e.* a trauma team) should supersede individual provider quality performance;
7. offer the capability for state, regional, or national aggregation so that results can assess variations in care and address population health and variabilities in a comparative manner;
8. provide a registry infrastructure that is audited, has demonstrated methodological rigor , reliability, and data validity;
9. serve all payers and patients, not just Medicare or other specific populations;
10. contain registry based measures and, if appropriate, they would be submitted to NQF for endorsement;
11. contain a secure authentication method that increases the usability of the data for evaluation and QI;
12. allow for transparency of registry data elements, performance measure specifications, and risk adjustment methodologies (if relevant), achieved by publishing or otherwise making this information publicly available; and

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ACS has demonstrated these standards through ACS NSQIP, which has enabled successful longitudinal quality measurement, allowing for data reuse to track (participating) hospital performance over time for valid comparison of outcomes among all hospitals in the program. ACS NSQIP also provides continuously updated hospital performance reports and nationally benchmarked and risk-adjusted reports.

Patient-level Data. CMS proposes that the registry provides access to the qualified clinical data registry database or a copy of the actual data. **We seek clarification on how CMS defines “patient-specific data,” and whether CMS is proposing that entities submit patient-level data that is de-identified, or contains patient identifiers. As discussed above, we do not think that this is in line with the Congressional intent to provide patient-level data with identifiers and/or raw data.**

Validation Strategy. CMS proposes to require entities to submit an acceptable “validation strategy” that would detail how the QCDR will determine whether EPs succeed in reporting clinical quality measures. As mentioned, we believe that a robust validation strategy is critical to verifying the rigor of the data, and negates the need for CMS to review patient-level and/or raw data. **However, we seek further clarification from CMS on what will be required as part of the validation strategy and whether participant attestation is acceptable. We also ask CMS to clarify whether the proposed validation strategy requirements for the QCDR are the same as the 2013 Qualified Registry Based Reporting validation strategy requirements.**

Data Privacy. As a requirement to participate as a QCDR, CMS proposes that entities must describe its plan to maintain Data Privacy and Security for data transmission, storage and reporting, and comply with the CMS-specified secure method for quality data submission. **We ask CMS to clarify if these proposed privacy and submission requirements for the QCDR are the same as the 2013 Qualified Registry Based Reporting option requirements finalized in the CY 2013 PFS Final Rule.**

Auditing Criteria. CMS proposes that entities make available samples of patient-level data for auditing purposes. CMS also proposes that if, during an audit, they find that a QCDR has submitted inaccurate data, that they will disqualify the clinical data registry. **ACS seeks clarification on what CMS considers to be “inaccurate data.”** For the 2013 Qualified Registry Based Reporting option which was finalized in the CY 2013 PFS Final rule, CMS provided the examples of “grossly inaccurate data” as inaccurate tax identification numbers or National Provider Identifiers on five percent or more

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of the registry submission. **We ask CMS to clarify whether the proposed auditing criteria will be the same as the 2013 Qualified Registry Based Reporting option requirements finalized in the CY 2013 PFS Final Rule.**

Data Submission. CMS proposes that the QCDR will be required to submit data no later than the last Friday occurring two months after the end of the respective reporting period. **We ask that CMS provide further clarification on measures which have longer follow-up periods, such 60 days or 90 days. We recommend that CMS includes language to account for longer follow-up periods.** For example, the QCDR should be required “to submit data no later than the last Friday occurring 2 months after the end of the respective reporting period for all completed cases, as detailed in the registry measure specifications” (that is, for cases with a 90-day follow-up period that began in December 2014, the case would be closed in March 2015, and reported to CMS by February 27, 2016).

Measure Reporting Thresholds. For satisfactory reporting of quality measures under the QCDR reporting option, CMS proposes the following criteria: report at least nine measures covering at least three of the NQS domains and report each measure for at least 50 percent of the EP’s eligible patients for a 12 month reporting period. Of the measures reported via a clinical registry, at least one outcome-based measure must be reported.

ACS believes that reporting a minimum of nine measures is too high. Instead of increasing the minimum reporting requirement to nine measures, ACS thinks that CMS should consider making the requirement to report on three NQS domains. While we do not believe CMS should replicate PQRS reporting requirements in the QCDR criteria, we do believe there is an opportunity to place more emphasis on the number of NQS domains in which measures are reported rather than the total number of measures.

NQS Domain Determinations. It is unclear from the proposed rule how measures utilized in the QCDRs will be assigned to the NQS domains. **ACS believes that the responsibility to determine the appropriate NQS domain for each QCDR measure should be given to the QCDR collecting the data.** The QCDRs will be best suited to determine which NQS domain is appropriate for their measures.

Categories of Measures. For satisfactory reporting of quality measures under the QCDR reporting option, CMS proposes that the registry must report on a set of measures from one or more of the following categories: CG-CAHPS; NQF-endorsed measures, current PQRS measures; measures used by boards or

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specialty societies; and measures used in regional quality collaboratives. **In addition to CG-CAHPS, ACS strongly urges the inclusion of the S-CAHPS as an option for satisfactory reporting.** If S-CAHPS is included as an option in the QCDR, it will be voluntary, which would allow physicians to select the patient experience of care survey that is most appropriate for their patient population. Physicians could then choose the CAHPS best-suited to the care they deliver.

S-CAHPS has been tested by the same standards as the CG-CAHPS, follows the same collection mechanism as the CG-CAHPS and is just as accurate. The S-CAHPS expands on the CG-CAHPS by focusing on aspects of surgical quality that are important from the patient's perspective and for which the patient is the best source of information. The survey asks patients to provide feedback on surgical care, surgeons, their staff, and anesthesia care. It assesses patients' experiences with surgical care in both the inpatient and outpatient settings by asking respondents about their experience before, during and after surgery.

Public Reporting Requirements. CMS proposes that the entity must demonstrate that it has a plan to publicly report quality data through a mechanism where the public and registry participants can view data about individual EPs, as well view regional and national benchmarks. We urge CMS to reconsider the requirement that the entity must “demonstrate a plan to publicly report their quality data through a mechanism where the public and registry participants can view data about individual EPs, as well as regional and national benchmarks.” We believe that this requirement will make it very difficult for patients to locate information on providers, reducing transparency and increasing the proliferation of multiple sources with multiple formats and different standards. **To this end, ACS believes that CMS is better situated to publicly report this information on the Physician Compare which will provide a standardized, and central portal for information on providers.**

We also recommend that CMS implement a phased approach to the requirement to publicly reporting participant data. We believe it would be more feasible to report data from registries after one year of participating as a QCDR. This will allow entities to gain experience in collecting and reporting data to CMS, resolve any inaccuracies in the reported data, and allow participants the opportunity to review quarterly feedback reports prior to publicly posting data on their performance. We believe this course of action will increase participation by building provider trust.

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Lastly, we believe that while CMS only contemplates the participation of individual EPs, a QCDR should be able to fulfill the public reporting requirements by reporting on a group practice. **ACS urges CMS to allow registries to determine which type of reporting is clinically appropriate based on the type of care provided.** For many specialties, reporting at the level of the group acknowledges that healthcare delivery is an outcome of the actions of many individuals and the systems that support them.

Benchmarking. As part of this recommendation, CMS also proposes that the entity has the capacity to benchmark EPs, and notes that the capacity to benchmark nationally is preferable, although at a minimum the entity should possess the capacity to benchmark performance of EPs within the clinical data registry. The ACS shares CMS' preference for national and regional benchmarking. **The ACS does not support benchmarking within a QCDR. At a minimum, entities should be required to benchmark regionally, but risk-adjusted national and local benchmarks will provide physicians with the best data for analyzing and reporting their performance and to ultimately improve patient outcomes.** Our experience through NSQIP has shown that because NSQIP is based on the best available data—clinical, risk- and case-mix adjusted, nationally benchmarked and audited 30-day patient outcomes—the program provides arguably the most valid and reliable look at surgical quality that ensures what is reported is the most accurate picture of quality.

Timing of Provision of Data. CMS proposes to require a QCDR to provide CMS with quality measure performance that they collect from EP participants via a CMS specified file or format. As part of this recommendation, CMS explains that they considered the alternative that a QCDR provide CMS with a list of EPs (containing the respective tax identification number (TIN)/NPI information) who participated in and reported quality data to the QCDR in order to determine which EPs met the criteria for satisfactory participation for the 2014 PQRS incentive and the 2016 PQRS payment adjustment. CMS explains that they considered this alternative because they do not have experience collecting data for QCDRs, that they are unfamiliar with the type of data a QCDR would collect, and that they are still building infrastructure. ACS supports this alternative approach in order to allow CMS to build the infrastructure and gain expertise in collecting data from clinical data registries. **Therefore, ACS agrees that in the first year of operation as a QCDR entities should only be required to provide a list of individuals who met the criteria for successful participation and should not be required to submit quality measure data to CMS for the 2014 incentive and 2016 PQRS payment adjustment. To this end and to assist in the transition, we**

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recommend that for purposes of the value-based payment modifier, providers who get credit for PQRS via participation in a QCDR would receive a quality domain score of “average” in order to provide more time for CMS to contemplate how to provide a quality score based on the varied performance measures that could be included in QCDRs.

Physician Value-Based Payment Modifier and the Physician Feedback Reporting Program

Proposals for Additions and Refinements to the Existing Value-Based Payment Modifier

Beginning January 1, 2015, the Secretary is required to apply a value-based payment modifier to specific physicians and groups of physicians the Secretary determines are appropriate. The Secretary is then required to apply the payment modifier to all physicians and groups of physicians by 2017.

Overview

With respect to quality tiering, the proposed rule states that groups of physicians will be eligible for the additional +1.0x if the groups’ attributed patient population has an average beneficiary risk score in the top 25 percent of all risk scores and the group of physicians provide care in the high quality/low cost tier (resulting in payment adjustment of +3.0x instead of +2.0x), average quality/low cost tier (resulting in payment adjustment of +2.0x instead of +1.0x) or high quality/average cost tier (resulting in payment adjustment of +2.0x instead of +1.0x). **We strongly urge CMS to allow all groups of physicians to be eligible for the additional payment across all quality/cost categories under quality tiering if the groups’ attributed patient population has an average beneficiary risk score in the top 25 percent of all risk scores.** We believe that no physician group that takes on the risk of furnishing care to high risk Medicare beneficiaries should be penalized compared to other groups. In addition, uncertainty as to whether a group will receive the payment for taking on high risk patients could dissuade groups from electing quality tiering or even from providing care to such patients.

The proposed rule also notes that this additional upward payment adjustment (+1.0x for the CY 2015 payment adjustment period) will not apply to groups of physicians that select the PQRS Administrative Claims reporting mechanism in CY 2013 for the CY 2015 payment adjustment. **As stated above, while we strongly believe the upward adjustment should apply to all physicians that take on high risk patients, as defined by CMS, we believe it is critical, at**

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the very least, to apply the upward payment adjustment to those groups of physicians whose attributed patient population has an average risk score in the top 25 percent of all risk scores and select administrative claims and quality tiering for the CY 2015 payment adjustment and fall into the low cost/high quality, average cost/high quality, or low cost/average quality tiers. It is fundamentally unfair to not allow these groups to be eligible for the additional upward adjustment simply because they selected to report via Administrative Claims.

Approach to Setting the Value-Based Payment Modifier Adjustment Based on PQRS Participation

Group Reporting by Individuals

CMS proposes that a group of physicians subject to the CY 2016 modifier would be considered successful PQRS reporters for the purposes of the value-based payment modifier if at least 70 percent of the individual EPs in the group avoid the CY 2016 payment adjustment by any of the available reporting options available under the PQRS. In addition to other reasons, CMS proposes the 70 percent threshold because the agency believes that it will obtain a reliable indicator of the group's quality if at least 70 percent of the EPs meet the criteria to avoid the PQRS payment adjustment and, based on 2011 data, 63 percent of groups of 50 or less EPs are already meeting the 70 percent threshold.

We urge CMS to reduce this threshold to 50 percent. Because the value-based payment modifier is still in its infancy, setting a high bar for this aspect of the proposal is not ideal. Rather than starting at a level where 63 percent are successful, we urge CMS to make this policy of group reporting by individuals more accessible, especially given CMS' statement in the CY 2014 PFS proposed rule that the vast majority of EPs participate in PQRS as individuals.

Although CMS states that the 70 percent threshold is necessary for obtaining a reliable indicator of the group's quality, we believe a lower threshold can still provide a reliable indicator. For example, if a multi-specialty group comprised of primary care physicians and specialists were to report via the GPRO web-interface option, the 22 measures included in this option may not provide an accurate gauge of the quality provided by the specialists in the practice. In this instance, if 50 percent of the EPs reported on measures applicable to their relevant specialties, this would likely produce a much better assessment of the group's quality compared to the 22 GPRO web-interface measures, which are focused on primary care.

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The threshold for a reliable indicator of the group's quality could also vary by group and the measures that the group selects. **Because it is unclear what the appropriate threshold would be given the various groups and applicable measures, we urge CMS to choose a fair threshold of 50 percent for the initiation of this policy.**

Finally, we ask that CMS clarify that the individual reporting mechanism of reporting three measures to avoid the CY 2016 penalty is also an applicable individual mechanism for purposes of the value-based payment modifier, despite the fact that this mechanism is not described in the CY 2014 PFS Proposed Rule.

Quality Tiering Methodology and Payment Adjustment Amount

CMS proposes to require that groups considered successful PQRS reporters for the purposes of the value-based payment modifier would be subject to mandatory quality tiering. CMS also proposes that the quality tiering downward payment adjustment amount would change from -1.0 percent to -2.0 percent for high cost/low quality groups and from -0.5 percent to -1.0 percent for both average cost/low quality and high cost/average quality groups. CMS proposes that groups of 10-99 EPs would only be subject to upward or no adjustments, and that groups of 100 or more EPs would be subject to upward, downward, or no adjustments.

While we understand the need for a downward adjustment in order to provide for the upward adjustments, given the budget neutrality requirements, we urge CMS to not make the proposed changes to the quality tiering downward adjustments. **That is, we request that the downward payment adjustment amounts remain at the CY 2015 payment year rates of -1.0 percent for high cost/low quality groups and -0.5 percent for both average cost/low quality and high cost average quality groups.** Because this is the first time that many groups will be quality tiered, it is important to encourage participation by not making the penalties too steep in the early years of implementation of this policy.

We also reiterate the need to allow *all* groups of physicians who elect quality tiering to be eligible for the additional +1.0x across all quality/cost categories if the groups' attributed patient population has an average beneficiary risk score in the top 25 percent of all risk scores. Despite the fact that groups will have access to their Physician Feedback Reports, not all groups will be able to make necessary improvements. Given that the Hierarchical Condition Category (HCC) risk adjustment model has

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shortcomings, it is not fair to further penalize the groups that are struggling the most. As such, we continue to stress the necessity to allow all groups, regardless of quality tier, to receive the additional +1.0x if the groups' attributed patient population has an average beneficiary risk score in the top 25 percent of all HCC risk scores.

Performance Period

Currently, CY 2013 is the performance period for the CY 2015 payment adjustment and CY 2014 is the performance period for the CY 2016 payment adjustment. CMS proposes that CY 2015 would be the performance period for the CY 2017 payment adjustment. Our previous comments expressed concern about the gap between the end of the performance period and the beginning of the payment adjustment period. We very much appreciate CMS' response to our comment, the description of the steps required to shorten this gap, and CMS' dedication to using available means to address this problem.

We continue to stress that CMS seek ways to reduce the time between the performance period and the adjustment period. The length of this gap makes it challenging for the value-based payment modifier to be actionable, which is one of CMS' stated principles governing the implementation of the value-based payment modifier. Lessons learned from performance in early CY 2013 will be difficult for EPs to remember, let alone relate to an adjustment in CY 2015. We believe that closing the gap is crucial, and that adjusting the performance periods would be helpful. We commend CMS' efforts at implementing a nine-month gap between the performance and adjustment periods for hospital value-based purchasing. Although this is a different program, perhaps some of the approaches used on the hospital side could be applied to the physician value-based payment modifier. Regardless, we encourage CMS to continue to strive to find new ways of reducing the time between the value-based payment modifier performance period and the adjustment period.

Quality Measures

We appreciate CMS' flexibility in allowing performance on all PQRS measures (and possibly other measures that are reported through the PQRS qualified clinical data registry option) to be included in the value-based payment modifier; however, we have some concerns with the inclusion of inappropriate measures in the program. **We urge CMS to delay the inclusion of new measures in the value-based payment modifier for a year so that problems associated with the measure can be identified.**

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By way of comparison, measures included in the hospital value-based purchasing program must be selected from the pool of measures already approved for the Hospital Inpatient Quality Reporting (IQR) Program, and these measures must have been displayed on Hospital Compare for at least a year. This allows hospitals to be on notice that these measures could impact their payment and allows any potential issues to surface. For example, in the FY 2014 Inpatient Prospective System rule, CMS removed several measures from the Hospital IQR for reasons including lack of NQF endorsement, recommendation by the MAP for removal, inadequate link to patient outcomes, challenges in validating efficiency, lack of feasibility to implement in light of new practice guidelines, and availability of other more meaningful measures. It is crucial that such inadequate measures are removed prior to being used for payment under the Hospital value-based purchasing program.

While we do not believe it is necessary or helpful to require that all value-based payment modifier measures be included on Physician Compare for a year, we do believe that physicians should have the opportunity to report on or otherwise observe how they perform on the measures for a period of time before they are used for payment adjustments under the value-based payment modifier.

All-Cause Hospital Readmissions

In the CY 2013 PFS final rule, CMS finalized the inclusion of an All Cause Hospital Readmissions Measure as one of three outcome measures for the calculation of the quality composite for the purposes of quality tiering. The ACS did not support the inclusion of this measure in our comments to CMS last year. **We explained that while we agree that reducing preventable readmissions will bring down healthcare costs, we do not support the inclusion of the readmission measure in the valued-based payment modifier the reasons listed below.**

First, the effect of case mix on this measure is currently unproven. The measure does not adequately account for socioeconomic factors and resource use of heavily burdened hospitals that care for disadvantaged populations, which may unfairly impact such institutions. Second, the HWR models are broad with respect to populations evaluated, yet constrained to one outcome of uncertain and unproven meaning. As such, the HWR measure is not aligned with current modeling considerations focused on patient subgroups and their related risk factors and outcomes. It is generally accepted in most medical

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disciplines that focused risk adjustment algorithms perform best when applied to focused patient populations.

A recent article in the Journal of the American Medical Association (JAMA) regarding risk prediction for hospital readmission noted that “readmission risk prediction remains a poorly understood and complex endeavor. Indeed, models of patient-level factors such as medical comorbidities, basic demographic data, and clinical variables are much better able to predict mortality than readmission risk. Broader social, environmental, and medical factors such as access to care, social support, substance abuse, and functional status contribute to readmission risk in some models, but the utility of such factors has not been widely studied.”²¹ In addition, “most models created to date, whether for hospital comparison or clinical purposes, have poor predictive ability. Although in certain settings such models may prove useful, better approaches are needed to assess hospital performance in discharging patients, as well as to identify patients at greater risk of avoidable readmission.”²² In further support of not including this measure, the MAP has recommended against including the measure in the calculation of the value-based payment modifier because it has not been “tested and endorsed for clinician level measurement.”²³ Therefore, we do not support the inclusion of this measure in the value-based payment modifier.

2016 Participation in a Qualified Clinical Data Registry (QCDR)

If all the EPs in a group of physicians subject to the CY 2016 value-based payment modifier satisfactorily participate in a QCDR in CY 2014, and CMS is unable to receive quality performance data for those EPs for purposes of the value-based payment modifier as they would for EPs participating in PQRS through one of the traditional reporting options, **CMS proposes to classify the group’s quality composite score as “average” under the quality tiering methodology. We support this proposal, and we agree that it is a reasonable way to address the problem of CMS potentially not being able to tier groups under the proposed QCDRs.**

²¹ Kansagara at al., Risk Prediction Models for Hospital Readmission, 306(15) JAMA 1688, 1695 (2011)

²² Id. at 1697.

²³ National Quality Forum. “Measure Application Partnership: Clinician Workgroup Web Meeting.” Web Meeting, April 1, 2013. Available at http://www.qualityforum.org/Setting_Priorities/Partnership/Clinician_Workgroup/Clinician_Workgroup_Meetings.aspx.



Inclusion of the Medicare Spending per Beneficiary Measure in the Value-Based Payment Modifier Cost Composite

Construction of the MSPB Measure

In the 2013 PFS CMS finalized five cost measures in the part of the value-based payment modifier cost composite including total per capita costs (both Parts A and B) and total per capita costs for beneficiaries with four specific chronic conditions: Chronic obstructive pulmonary disease (COPD), heart failure, coronary artery disease (CAD), and diabetes. For CY 2014, CMS proposes to expand the cost composite to include the MSPB as an additional measure to be added to the total per capita cost domain. As a result, there would be two measures in this domain: the total per capita cost measure and the MSPB measure. The MSPB is currently finalized in the IQR and VBP programs. The MSPB measure is triggered by an inpatient hospitalization and includes all Medicare Part A and Part B payments during an MSPB episode which is 3 days prior to the index admission and 30 days post-discharge. The rationale that CMS provides for inclusion of this measure is that Medicare spending post-hospital discharge is a significant source of variation in MSPB measure rates, and the measure will enable CMS to assess groups of physician's performance related to post-acute care spending. **ACS does not support the inclusion of the MSBP measure in the value-based payment modifier for the reasons listed below.**

The rationale provided for inclusion in the value-based payment modifier is that it will enable CMS to assess groups of physician's performance related to post-acute care spending. However, the measure will not capture efforts by physicians to minimize hospital admissions. Physicians who successfully managed the majority of their patients by preventing admission could be tiered as a high cost provider because it is likely that only their sickest patients are included in the value-based payment modifier cost composite, resulting in misclassification of physician care. This is especially concerning for EPs who will be scored solely on the MSPB measure for the value-based payment modifier cost calculation.

Furthermore, ACS has concerns regarding the validity of the MSPB measure. The risk adjustment methodology does not adequately account for socioeconomic status (SES) and therefore does not consider the ranges of patient complexity and circumstances that are out of the provider's control. As a result, the lack of risk adjustment for SES may unfairly impact providers that care for disadvantaged populations. Concerns regarding the lack of adjusting for SES were also expressed during NQF-endorsement by the Cost and

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Resource use Steering Committee which was split on their vote for the validity of the measure.

Additionally, ACS is concerned this measure lacks validity and reliability as a physician-level measure. The measure was designed and tested as a facility-level measure and should be tested for validity and reliability as a physician-level measure prior to inclusion in the value-based payment modifier. The NQF Cost and Resource Use Steering Committee has also expressed concern regarding implementation of the MSBP measure as a physician-level measure. We strongly recommend that the measure be re-specified and tested as a physician-level measure and be reported in PQRS for one year prior to inclusion in the value-based payment modifier. In addition, the MAP has not approved the use of this measure in the physician setting. The ACS opposes CMS' persistent reliance on measures that were never developed for and tested in physician practices, especially in the absence of any CMS analysis of how these measures affect different types of practices and in the context of a mandatory, rather than an optional, tiering process.

Attribution of the MSPB Measure to physician groups

Given our strong reservations about the inclusion of the MSBP measure in the value-based payment modifier as described above, it is difficult to comment on the most appropriate attribution methodology. However, we believe the least useful is the option whereby CMS would attribute an MSPB episode to a group of physicians subject to the value-based payment modifier when any EP in the group submits a Part B claim under the group's TIN for a service rendered during an inpatient hospitalization that is an index admission for the MSPB measure during the performance period for the applicable calendar year payment adjustment period. This option will provide CMS with no useful information on which providers are actually responsible for the costs associated with the patient. If anything, this approach could provide misinformation because it treats a group that could have provided the vast majority of the services to a patient the same as a group where one of the EPs saw the patient once. It is also unclear whether this method would attribute the entire episode multiple times to the same group if more than one EP from that group were to submit Part B claims under the group's TIN. In addition, there is no guidance from CMS on how it would treat the costs for services received by the patient within the three/30 day window for services that are unrelated to the index admission.

CMS also offers two alternative approaches: the plurality and the hybrid attribution options. Under the plurality approach, CMS would attribute the

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MSPB episode solely to the group of physicians that provided the plurality of Part B services billed. The hybrid approach would attribute the MSPB episode to all TINs from which an EP provided services representing at least 35 percent of the total Medicare Part B payments. The drawback of these approaches is that they only include services related to admissions, to the exclusion of all other services that a physician may provide. As such, we have concerns about the ability of each of these approaches to adequately attribute the cost associated with this measure and we urge CMS to not include this measure in the value-based payment modifier. If CMS does proceed with including this measure, we recommend that CMS use the attribution methodology currently used for the other cost measures, namely, attributing the costs to the group that provides the plurality of E/M services. We also urge CMS to fully test this measure and the attribution methodology, in addition to providing feedback to physicians, before including this as a payment adjuster under the value-based payment modifier.

Refinements to the Cost Measure Composite Methodology

Attribution of fewer than 20 beneficiaries

CMS has observed that groups of physicians that do not provide primary care services are not attributed beneficiaries or are attributed fewer than 20 beneficiaries for purposes of the value-based modifier cost measures. **CMS proposes that if the agency is unable to calculate any of the cost measures with at least 20 cases, the group's cost composite score would be classified as "average" under the quality tiering methodology. We agree with CMS that this policy is reasonable because the agency would have insufficient information to classify the group's cost as high or low and we support this proposal.**

Refinements to the benchmark

Using 2011 claims data, CMS has found that using a national mean as a benchmark and comparing all groups to that mean could have varied impacts on different groups because some specialties are almost always more or less expensive than average. CMS discusses two methods to account for the group practice's specialty composition: the "specialty adjustment," which would create a benchmark for each specialty for each cost measure, and the "comparability peer grouping," which would combine similar groups based on certain specified criteria.

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We appreciate that CMS has recognized the disparate impact that the current benchmarking policy could have on different specialties, and we appreciate CMS' proposed alternative methods. One issue regarding the "specialty adjustment" is that there can be wide variation within a certain specialty. For example, transplant surgeons typically enroll in Medicare as general surgeons (02-General Surgery), but the costs of transplant surgeons will almost always be higher than the costs of non-transplant general surgeons, thereby forcing them toward the high cost tier of quality tiering.

CMS acknowledged a similar problem with the "comparability peer grouping" in that if there are not enough similar groups, a group or groups could be combined with the nearest comparable specialty mix. The "comparability peer grouping" could still be a reasonable way to benchmark, but it is difficult to comment without knowing what criteria CMS plans to use to determine comparable peer groups.

If CMS proceeds with the "specialty adjustment" approach, one way that CMS could solve the problem of groups being on the "edge" of a grouping is by identifying the top 15 codes that specialists within a specialty bill and creating additional benchmarks if needed within a specialty. In that way, more expensive transplant surgeons could be differentiated from the non-transplant general surgeon and each would be compared to other groups that provide similar services. This option could be seen as a hybrid of the "specialty adjustment" and the "comparability peer grouping." We urge CMS to give consideration to this approach of classification by top codes that a group bills, which we believe is the fairest way to truly compare groups and the services they provide.

Physician Feedback Program

In CY 2012, CMS disseminated feedback reports to both groups and individual physicians based on CY 2011 performance. In September, 2013, CMS plans to provide feedback reports at the TIN level to all groups of physicians with 25 or more EPs, based on CY 2012 data. CMS plans to disseminate feedback reports based on CY 2013 data to all physicians in late summer of 2014, which will include performance on quality and cost measures used to score the composites of the value-based payment modifier.

We appreciate that CMS is making these reports available to all physicians in 2014. Although a successful physician feedback report program is an essential component of the value-based payment modifier, it is not clear that this information will be provided in time to inform physicians about their 2013

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utilization, which is the basis for the 2015 payment period. Groups are required to make the decision whether to quality tier in December of 2013 for the purposes of the 2015 payment adjustment, yet will not receive data on their performance until late summer of 2014, making it difficult for them to make that choice.

We appreciate the opportunity to comment on this proposed rule. The ACS looks forward to continuing dialogue with CMS on these important issues. If you have any questions about our comments, please contact Bob Jasak, Deputy Director for Regulatory and Quality Affairs in the ACS Division of Advocacy and Health Policy. He may be reached at bjasak@facs.org or at (202) 672-1508.

Sincerely,

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