SURGICAL QUALITY ALLIANCE

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August 8, 2011

Donald M. Berwick, MD, MPP
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-5059-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; Availability of Medicare Data for Performance Measurement

Dear Dr. Berwick,

On behalf of the undersigned surgical specialty societies, the Surgical Quality Alliance (SQA) appreciates the opportunity to submit comments to the proposed rule: *Medicare Program; Availability of Medicare Data for Performance Measurement*, which was published in the *Federal Register* on June 8, 2011. The SQA is a collaborative effort of over 20 surgical and anesthesia specialty societies united to define the principles of surgical patient quality measures, share methodologies to assist in the development of meaningful tools for quality improvement, and provide a forum for shared and coordinated efforts among the specialties to monitor and respond to federal and private sector initiatives.

The proposed rule implements section 10332 of the *Patient Protection and Affordable Care Act (ACA)* that will make Medicare claims data available for the purpose of allowing Qualified Entities (QEs) to prepare publicly available evaluations and comparisons of provider performance. However, Section 10332 does not mandate the release of data for all Part B suppliers. Physician claims data should not be released because that information is private financial information that is protected from disclosure by the Privacy Act. Further explanation of the violations to the Privacy Act release of this data would cause is discussed in further detail below. For purposes of evaluating specific provisions of the proposed rule, however, our comments will assume that CMS may release the data. To this end, the SQA supports efforts to help physicians and patients better understand the quality and cost of their care and to provide them with tools that will allow for the continuous improvement of care only if appropriate safeguards are in place to guarantee the accuracy and validity of the performance reports that will be made publicly available.

In addition, while we understand that the Centers for Medicare and Medicaid Services (CMS) is required by ACA to address the issue of the release of claims data, we hope

the Agency recognizes the better value of using clinical data often available via registries and incorporates that more meaningful data into its value-based purchasing programs. There are three main problems with administrative claims data: (1) documentation by the physician, (2) coding on the hospital's part, and (3) attribution. It is often unclear from claims data which physician served as the primary surgeon or anesthesiologist and which served as the assistant. The second issue is the inconsistency in coding. Coders are supposed to use the same code books, but the coder often must interpret what the physician has documented, which results in inconsistency. As an example, three coders may look at the same chart and have three different opinions on which constitutes proper coding. The problem with attribution is that there is no standardized methodology to appropriately attribute patient episodes of care among the several providers who participate in the care, and CMS does not have a protocol for attribution. The SQA urges CMS to hold a national forum to settle issues related to attribution.

A recent study examined the validity of patient safety indicators (PSI) with Veterans Health Administration (VA) administrative data, and found that the positive predictive value of PSIs because they rely on administrative data are inconsistent and variable and, therefore, researchers recommend that coding schemes should be modified before using them for clinical or quality care purposes.[1] These findings are consistent with private sector studies.[2] Furthermore, CMS has also recognized the limitations of claims-based data, acknowledging that it has been created for billing purposes and not for quality reporting, and therefore supports the use of a registry-reporting mechanism.[3] Because of better reliability, the SQA has consistently supported the use of clinical and registry data over claims data, and at some point in the near future, under a standardized, regulated process, QEs should also be permitted to incorporate non-administrative data sources into their reports. Such data helps paint a more accurate picture of the quality of care being provided to patients.

[1] Kaafarani, H. M. A., Borzecki, A. M., Itani, K. M. F., Loveland, S., Mull, H. J., Hickson, K., et al. (2011). Validity of selected patient safety indicators: Opportunities and concerns. *Journal of the American College of Surgeons, 212*(6), 924-934.

[2] Allison, J. J., Wall, T. C., Spettell, C. M., Calhoun, J., Fargason, C. A.,Jr, Kobylinski, R. W., et al. (2000). The art and science of chart review. *The Joint Commission Journal on Quality Improvement, 26*(3), 115-136.; Henderson, K. E., Recktenwald, A., Reichley, R. M., Bailey, T. C., Waterman, B. M., Diekemper, R. L., et al. (2009). Clinical validation of the AHRQ postoperative venous thromboembolism patient safety indicator. *Joint Commission Journal on Quality and Patient Safety / Joint Commission Resources, 35*(7), 370-376.; Kaafarani, H. M., & Rosen, A. K. (2009).; Using administrative data to identify surgical adverse events: An introduction to the patient safety indicators. *American Journal of Surgery, 198*(5 Suppl), S63-8.; Utter, G. H., Zrelak, P. A., Baron, R., Tancredi, D. J., Sadeghi, B., Geppert, J. J., et al. (2009). Positive predictive value of the AHRQ accidental puncture or laceration patient safety indicator. *Annals of Surgery, 250*(6), 1041-1045.; Weller, W. E., Gallagher, B. K., Cen, L., & Hannan, E. L. (2004). Readmissions for venous thromboembolism: Expanding the definition of patient safety indicators. *Joint Commission Journal on Quality and Safety, 30*(9), 497-504.; White, R. H., Sadeghi, B., Tancredi, D. J., Zrelak, P., Cuny, J., Sama, P., et al. (2009). How valid is the ICD-9-CM based AHRQ patient safety indicator for postoperative venous thromboembolism? *Medical Care, 47*(12), 1237-1243. ; Zhan, C., Battles, J., Chiang, Y. P., & Hunt, D. (2007). The validity of ICD-9-CM codes in identifying postoperative deep vein thrombosis and pulmonary embolism. *Joint Commission Journal on Quality and Patient Safety / Joint Commission Resources, 33*(6), 326-331.

[3] Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011, 75 Fed. Reg. 40170 (2010)

In recognition of many of the critical factors that must be resolved regarding making performance information public, Congress included a number of requirements in section 10332 that are discussed at length below. As CMS moves forward to implement section 10332, we urge CMS to carefully develop a final rule in which QEs: (1) meet each of the requirements in section 10332; (2) produce public reports that are valid, meaningful, actionable, and user-friendly; and (3) participate in a reporting program that is standardized and streamlined to minimize administrative burden and allow comparable results. We urge that CMS move toward standardization of many elements QEs will use in developing and releasing public reports, including standardization of: measure specifications; the content of public reports; formatting of the reports; risk-adjustment and attribution methodologies; and appeal processes. It is also critical that the standardization process be applied across all payers, including Medicare and private payers.

Assuming that CMS may release physician claims data to QEs, our comments on issues of interest to the undersigned organizations are presented in the order in which they appear in the proposed rule.

CONSIDERATIONS FOR THE DEFINITION, ELIGIBILITY CRITERIA, AND OPERATING REQUIREMENTS OF QUALIFIED ENTITIES

Eligibility Criteria

CMS proposes eligibility criteria for an organization to be considered a QE that would gain access to claims data. These criteria fall under the categories of organizational and governance capabilities, the addition of claims data from other sources, and data privacy and security requirements. We support the criteria that CMS has enumerated under these three broad categories, but we additionally encourage CMS to seek public input on the applicants for QE status. Public input could be solicited through public notice. Due to the sensitive nature of the Medicare claims data, we urge CMS to maintain the strict eligibility criteria proposed for QEs. Lowering the standards or reducing the restrictions related to eligibility criteria could result in infringement of the privacy and security of beneficiary identifiable data and/or the unfair misrepresentation of the physicians who care for them. Although we support the criteria outlined by CMS, we seek clarification on the process for assessing a QE's ability to meaningfully utilize claims data. Specifically, we request further information on how CMS will determine that QEs must demonstrate that it has been handling claims data and calculating performance measures for a minimum of three years.

Regarding the addition of claims data from other sources, it is critical that the same analytic standards and safeguards apply to all sets of data. Measures applied to private payer data must come from the same standardized set as those used under Medicare (i.e., developed through a consensus-based, physician-led process). The risk-adjustment and attribution methodologies applied should also adhere to consistent, reliable, and previously agreed upon formats. Processes must be put in place to ensure the seamless integration of private payer and Medicare data. When data are combined from various sources, it is also critical that performance analyses remain transparent about the sources of the data and the mechanisms used to combine that data. To this end, the SQA urges CMS to include a requirement that data should not be passed on successively to multiple organizations as part

of the final rule. We support CMS's proposal to require claims data from two or more other sources as a means to better ensure that performance reports produced by QEs are as fair a representation as possible of any provider's or supplier's practice to encourage behavior change.

When discussing the required alternative sources of data, CMS states that data from other sources such as registry data, chart abstracted data, or data from electronic medical records would not be considered. Given the proven advantages of clinical data, we strongly believe that clinical data registries should qualify to meet the eligibility criteria as an alternative data source. Many of the societies in the SQA have created robust clinical data demonstrated to improve health outcomes and reduce the cost of health care delivery. Because of the proven value of clinical data, we believe the policy of excluding this type of data as an alternative source is misguided.

CONSIDERATIONS FOR THE DEFINITION, SELECTION, AND USE OF PERFORMANCE MEASURES BY QUALIFIED ENTITIES

Proposed Definition of, and Process for Identifying and Approving Standard Measures for Use by Qualified Entities

CMS proposes to define "standard measure" to be a measure that can be calculated using only claims data that are: (1) endorsed by the National Quality Forum; (2) developed pursuant to section 931 of the Public Health Service Act; or (3) was adopted through notice and comment rulemaking and currently being used in a CMS program. Regarding those measures that are endorsed by the NQF, the SQA believes that measures should go through a multi-stakeholder endorsement process, and that measures should be developed through a rigorous and stringent process that is transparent, physician-led, and consensus-based. However, the SQA urges CMS to not limit the measure selection to National Quality Forum (NQF) endorsed measures. Given our commitment to development of measures through transparent, physician-led, and consensus-based process, we also believe that because there have not been any measures developed under section 931 of the Public Health Service Act these measures should not be considered acceptable. We urge CMS to define "standard measures" as those that are (1) supported by a multi-stakeholder endorsement organization using a transparent, physician-led, consensus-based process, or (2) adopted through notice and comment rulemaking and are currently being used in a CMS program and are well-tested for validity, acceptability, and feasibility. We strongly believe that until a measure is thoroughly tested in a clinical setting, it should not be used for public reporting purpose. To this end, we recommend CMS adopt a reasonable minimum time frame requirement for measures currently being used in a CMS program before becoming available for use by QEs. These requirements are critical to ensuring that entities use a common set of clinically relevant measures that have been properly evaluated for fairness and accuracy, and that can be aggregated and compared across broad populations for meaningful analysis.

Proposed Definition of, and Process for Identifying and Approving Alternative Measures for Use by Qualified Entities

CMS proposes to adopt an alternative measure selection process through future notice and comment rulemaking that would subject proposed alternative measures to public comment. In the interim, CMS proposes to define "alternative measure" as one that is not a standard measure, but that can be calculated using only standardized extracts of Medicare parts A, B, and D claims, and that has been found by the Secretary to be more valid, reliable, responsive to consumer preferences, cost effective, or relevant to dimensions of quality and resource use not addressed by the standard measures. CMS further proposes that QEs must use the standard measure for a clinical area or topic in lieu of any alternative measures unless a QE can provide detailed scientific justification asserting that the proposed alternative measure meets the definition of "alternative measure" above.

We have concerns with CMS' proposed use of alternative measures. If CMS permits the use of alternative measures under this program, the alternative measures should be used only on a provisional basis and when standard measures do not exist. One mechanism to achieve this could be for CMS to require a multi-stakeholder endorsement organization, such as the NQF, to conduct a rapid review during which "alternative" measures could be used by QEs only on a provisional basis until the measures are endorsed through the multi-stakeholder endorsement process within a certain timeframe (*e.g.*, 12-18 months). If the provisional measures are not endorsed within the set time period, their status as an "alternative measure" would lapse. Furthermore, we ask that CMS more specifically define the standards for all proposed measures.

Methodologies Used in Performance Reports

The ACA requires that QEs submit to CMS a description of the methodologies that they would use to evaluate the performance of providers and suppliers. CMS also proposes that QEs must demonstrate expertise and sustained experience in several areas necessary for performance measurement. The SQA appreciates the transparency offered under the statutory and regulatory provisions, but we believe CMS does not go far enough to ensure that QEs use methodologies that will produce accurate and valid performance reports. A description of the proposed methodologies and a demonstrated expertise and experience in some aspects of performance measurement alone may not necessarily result in the use of sound methodologies to generate reliable performance reports for this particular CMS program. Therefore, we strongly urge CMS to develop, in consultation with clinical experts and other relevant stakeholders, standardized methodologies which QEs will be required to use across both Medicare and private payer data to ensure that analyzed data are valid, reliable, and reproducible. Standardized measurement methodologies should be based on sound science and must take into account not simply cost, but also quality.

Proper attribution is especially important when measuring performance using claims data. As described earlier, it is not always clear from claims data which physician served as the primary surgeon or anesthesiologist and which served as the assistant. Because some claims are paid based on a group ID and not based on the individual provider's National Provider Identifier number, it is possible that a negative outcome related to a patient that a provider never saw could still be attributed to that provider. Further, many perioperative complications (e.g., postoperative peripheral neuropathy) cannot be reliably attributed to the actions of a single individual and are most appropriately assessed and reported at the team

level. Lastly, administrative claims data lacks the ability to "tell time." An example of this assumes that the patient is already in the hospital and has a complication or problem (such as a decubitus ulcer or HAI), and *then* has surgery. The surgeon can and will be tagged with the HAI or decubitus ulcer development even though this happened before the surgery. Accordingly, it is crucial that the methodologies should utilize accurate and well-tested risk-adjustment and attribution models, especially due to the high risk of public unfair representation of providers in the case of inaccurate performance reports.

DATA SECURITY AND PRIVACY

CMS is committed to ensuring that the beneficiary level data provided to QEs is subject to stringent security and privacy standards throughout all phases of the performance measure calculation, confidential reporting, appeal, and public reporting process. Therefore, CMS proposes to include in any data file provided to QEs an encrypted beneficiary identifier that would permit linking of claims for the same beneficiary across multiple files and multiple years without identifying individual beneficiaries. However, the statute permits providers to request of QEs the Medicare claims data underlying their measure results and therefore it would be difficult for providers to identify errors in measurement in the absence of patient names. CMS is considering three potential options for sharing beneficiary names with QEs, and by extension, providers of services and suppliers: (1) QEs would be provided with a crosswalk file linking all encrypted beneficiary identifiers to the patients' names; (2) CMS would only provide beneficiary names to QEs on a transactions basis for the purposes of responding to specific requests for data by providers; (3) providers who wish to receive beneficiary names would request the encrypted claims data from the QE as permitted under the statute, and then the provider would submit a request to CMS for the beneficiary names for those specific claims.

Due to the sensitive nature of the Medicare claims data, the SQA supports limiting the amount of data that is identifiable by the QE. However, the SQA strongly opposes Option 3, which would require the provider to file a request for beneficiary names to both the QE and CMS. Requiring providers to file the request for information unnecessarily complicates the appeals process. It is also unreasonable to require providers to perform these duties when providers are already subject to numerous administrative requirements related to claims submission and quality reporting. Furthermore, Option 3 diverts time and energy away from direct patient care which works in opposition to the goal of improving patient care.

CONFIDENTIAL OPPORTUNITIES TO REVIEW, APPEAL, AND CORRECT REPORTS

The ACA requires that QEs make their reports available confidentially to providers and suppliers identified in the reports prior to the public release of such reports, and to offer them the opportunity to appeal and correct errors. Additionally, the ACA requires that QEs release to providers who request it, the underlying Medicare claims data used to calculate the results for any measure the provider wishes to appeal. As a result, CMS proposes that as part of their application, applicants must include a plan for their process for confidential report review, appeals, and error correction processes. CMS proposes a five-element plan, which we discuss later in this section.

The SQA recommends an additional safeguard for accurate public reporting of quality measures. We strongly urge CMS to designate the first two years of this initiative as a formal test period. This scenario will allow for identification and resolution of issues and time for CMS to work with the both QEs and affected providers. The first year will allow stakeholders to arrive at mutually acceptable and scientifically valid ways to publicly report administrative claims data, and the second year will include testing of the appeals process. Without a test period, it is likely that inaccurate data will be reported to the public which could greatly affect the reputations of affected providers and provide patients with unreliable information. Furthermore, the test period will allow for investigation as to whether the reports will result in improved outcomes.

During the test period, providers, suppliers, and the public should be educated on the initiative, and made aware of the process to designate QEs, while providing feedback on the process. During this period, we propose that CMS choose a sample of QE applicants to produce confidential test year reports and allow providers to understand proposed measures and methodologies used to analyze and report data and to hear presentations of the reports. This process will allow for QEs to provide confidential feedback to providers and allow for proper scrutiny and discussion so that providers can understand the attribution and risk-adjustment methods. The process will also build provider trust. In addition, QEs should be required to analyze and report on a set of standardized Medicare sample data so that the public and providers can see how each QE's different methodology affects the results obtained and so appropriate safeguards can be put in place to minimize the range of results across QEs. Results of these reports should be presented in a format that allows for public input such as a town hall or open comment period.

The notion of a test period has precedence with NCQA's test year of rolling out any new measure before publicly reporting on it, as well as the PQRI Physician Feedback Program. The test period alternative proposed by SQA will likely ensure: (1) identification and timely resolution of differences in results from accepted methodologies by selected QEs; (2) resolution of any inaccuracies in results and report on providers; and (3) opportunities for providers to understand and engage in the process which should increase provider support.

As another safeguard, we strongly encourage CMS to provide notice to physicians and suppliers at the time when the QE has been approved to receive administrative data related to care provided by the physician. At this time, CMS should include a copy of the QE's prototype report so that providers and suppliers have the opportunity to review and familiarize themselves with the methodologies and format.

CMS Proposed Plan: Element 1

The SQA additionally has comments to CMS's proposed five-element plan for confidential report review, appeals, and error correction processes. Under the first element of the plan, a QE would be required to provide descriptions to inform providers and suppliers of the steps that were taken to generate their performance reports. This first element of the plan should include an explanation of the measurement methodology, estimates of statistical reliability, and information on how to interpret the results to help providers and suppliers understand their performance relative to their peers. We urge CMS to clarify in the final rule that these descriptions are required for Medicare and private payer data, and that the methodologies

used by QEs are standardized across Medicare and private payer data. If methodologies used by the QEs are not standardized, it is necessary for CMS to provide more detailed criteria regarding the methodologies themselves to ensure that the performance reports are fair, accurate, and reliable. This is crucial because a provider may appeal the content of their performance reports, but it is not clear whether a provider may appeal the methodologies used to generate the reports. As such, standardization or greater detail and safeguards are needed in the area of performance report methodologies.

CMS Proposed Plan: Element 2 and 3

The second and third elements of the plan require a QE to describe the means by which providers and suppliers may request the Medicare data that was used to calculate the performance measures they wish to appeal, and the means of confidentially sharing results with providers and suppliers (e.g., via Website or email). We support the second and third elements of the plan, but we urge CMS to require QEs to make a description of these means available to the public and not just to the specific provider receiving the performance report. The proposed rule does not describe any form of CMS education or outreach to providers regarding the performance reports, so it will be important for medical societies to develop and launch outreach efforts to assure that their members are educated on all aspects of the performance reports.

To give providers and suppliers access to the information required to accurately evaluate the report, we suggest CMS requires QEs to agree to one of the following options: (1) QEs provide two reports: the original report, which is one that can be easily interpreted by both patients and physicians, and a second more technical version, which includes necessary information for providers to calculate their own scores; or (2) as part of the initial agreement between CMS and the QE, the QE agrees to provide physicians with access to the underlying Medicare claims data used to calculate the results to providers and suppliers. Although we recognize that CMS might not have the statutory authority to require QEs to share data from outside sources, we recommend that CMS select entities that agree to provide data from outside sources upon request of the physician or supplier.

CMS Proposed Plan: Element 4

The fourth element of the plan requires a QE to provide a description of the means by which providers and suppliers can submit appeals for error correction. The proposed rule states that QEs must share measures, measurement methodology, and measure results with providers and suppliers at least 30 business days prior to making measure results public. Additionally, QEs must allow providers and suppliers at least 10 business days to make a request for the underlying data, and an additional 10 business days for a provider to request an error correction. We believe these timeframes are far too short. In essence, a provider would be required to understand the measurement methodology and identify all potential errors within 10 days in order to request the underlying data on time. The rule does not specify a timeframe by which the QE must respond to the request, but it should be clear that the provider has a set number of days to request a correction calculated after receipt of the data from the QE. Regardless, we urge CMS to allow providers 90 days to review the reports prior to making the reports publically available, at least 30 business days to request

data, and 30 days to request error selection. In addition, upon submission of subsequent changes to the prototype report to CMS, we urge CMS to prohibit QE publication of reports based on the new prototype for six months. Given the potential impact on a provider's practice and the potential to characterize providers in an unfavorable light and to influence value-based purchasing by consumers, it is imperative that providers have enough time to verify the accuracy of the performance reports. Additionally, the proposed rule permits each QE to determine its own appeals process. We believe that allowing for a multitude of appeals processes is very burdensome to providers and suppliers, and unnecessarily complicates the appeals process in general. We strongly encourage CMS to develop a standard appeals process to be implemented by the QEs.

CMS Proposed Plan: Element 5

The fifth element of the plan requires a QE to make clear to providers and suppliers that performance reports would be made public after a specified date, regardless of the status of any providers or supplier' requests for error correction. CMS also proposes to encourage QEs to dedicate appropriate resources, including qualified staff, to resolving good faith questions regarding performance results to both parties' satisfaction whenever possible. If the request for a data or error correction is still outstanding at the time of making the reports public, CMS proposes that the QE must, if feasible, post publicly the name of the appealing provider and a description of the appeal request.

We believe the proposed appeal process under the fifth element of the plan is inadequate. The only protection for providers who disagree with their performance reports is that CMS proposes to "encourage QEs to dedicate appropriate resources, including qualified staff, to resolving good faith questions regarding performance results to both parties' satisfaction whenever possible." If the QE chooses not to resolve the error in the performance report or if, in the QE's determination, resolving the error is "not feasible," the provider has no recourse. To make matters worse, the rule specifically allows QEs to make reports publically available after the specified date notwithstanding any pending appeal, but that the QE must only publically post a description of the appeal, "if feasible." It is critical that physicians are given an opportunity to discuss with the performance evaluator any questionable determinations and correct any errors prior to the data being released to the public, especially given the erroneous nature of using administrative data for performance assessment.

We also strongly believe that QEs should not be permitted to publish unresolved contested reports without the consent of the provider or supplier. However, if CMS allows publication under this scenario, we also believe that physicians should have the opportunity to include comments in the public report on the measure results, especially those being appealed. The lack of a true appeals process is unfair, especially given the very short timeframe to review the reports and the potentially adverse consequences of an inaccurate report to a provider's reputation and practice. In case QEs do not fairly or appropriately implement and administer an appeals process, CMS should develop a mechanism whereby providers can appeal to CMS for recourse.

In addition, the SQA requests that the Secretary work with physician experts and other relevant stakeholders to determine minimum appropriate standards for performance reports.

The format and content of such reports should be standardized across QEs and should result in the clear and comprehensible presentation of data and the analytic mechanisms used to derive that data. Reasonable and responsible oversight should be in place to ensure standardization amongst entities when publicly reporting on a physician's care. Without a standardized format, consumers will not be able to make apples to apples comparisons and will not be able to make well informed decisions about their care.

MONITORING, OVERSIGHT, SANCTIONING, AND TERMINATION

CMS proposes a monitoring program, which would assess QEs' compliance with the requirements laid out in the proposed rule and assess sanctions or termination as deemed appropriate by CMS. CMS proposes to periodically audit QEs' use of Medicare data for the production of performance reports, monitor the amount of claims data from other sources being used in the production of performance reports, and require QEs to submit an annual report to CMS covering general adherence to the program and engagement of providers and suppliers. We support CMS' efforts regarding monitoring of the program. We urge CMS to strictly enforce these requirements to protect the privacy and security of beneficiary identifiable data and to protect against the unfair misrepresentation of the physicians who care for them.

REGULATORY IMPACT ANALYSIS

Impact on Providers of Services and Suppliers

We believe that CMS is underestimating both the hourly costs and time involved for physicians and other providers to engage in the data release program. CMS estimates that providers will spend an average of five hours reviewing their performance reports and ten hours preparing appeals in cases where providers believe that their reports contain errors. We urge CMS to increase these estimates when evaluating the impact of the program on providers. In particular, we believe that the time required for a physician to prepare an appeal will exceed ten hours in the majority of cases, if the time required to pull and review patient charts is taken into consideration. CMS approximates the total hourly costs for physicians' offices to engage in reviewing and appealing performance reports to be $41.10. This figure significantly underestimates the financial impact of the program. Although certain administrative tasks, such as pulling patient records, may be performed by non-physician office staff, much of the work of reviewing and appealing reports will involve a physician's own time, for which an hourly rate of $41.10 represents a major undervaluation of physician labor. Additionally, the use of external consultants in the review process should also be included in the impact estimate since many small providers and suppliers will lack in-house analytic capacity.

ADDITIONAL CONSIDERATIONS

As discussed, section 10332 of the ACA requires CMS to release to QEs Medicare claims data for Parts A, B, and D. Section 10332 does not, however, mandate the release of data for all Part B suppliers. Physician claims data should not be released because that information is private financial information that is protected from disclosure by the Privacy

Act. 5 U.S.C. § 552a. CMS's longstanding policy has been that the Privacy Act protects this information, and this policy has been upheld by the federal courts. Section 10332 of the ACA must be implemented consistently with the Privacy Act, which requires that Qualified Entities not be given data on Medicare claims that could be used to determine the amount of Medicare payments made to individual physicians.

The Privacy Act generally prohibits a federal agency, such as CMS, from disclosing to members of the public electronic records maintained on an individual unless that individual consents to the release. 5 U.S.C. § 552a(b). CMS has consistently maintained that Medicare claims data constitute a "system of records" that is subject to Privacy Act protection. *See, e.g.*, 71 Fed. Reg. 64,955 (Nov. 6, 2006). Although the Privacy Act permits disclosure if required by the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, CMS has repeatedly refused to release physician claims data under FOIA on the grounds that such a release would constitute a "clearly unwarranted invasion of personal privacy." 5 U.S.C. §§ 552a(b)(2), 552(b)(6).

Two recent federal court of appeals decisions have addressed the release of physician claims data and upheld CMS's policy. *Consumers' Checkbook Center for the Study of Services v. United States Dep't of Health and Human Servs.*, 554 F.3d 1046 (D.C. Cir. 2009); *Alley v. United States Dep't of Health and Human Servs.*, 590 F.3d 1195 (11th Cir. 2009). In both cases, the courts upheld CMS's refusal to release physician claims data to entities that purportedly wanted to use the data to assess the quality of physician services. CMS invoked FOIA Exemption 6, 5 U.S.C. § 552(b)(6), on the grounds that releasing Medicare claims data would violate physicians' substantial privacy interest in their financial information. *Checkbook*, 554 F.3d at 1049; *Alley*, 590 F.3d at 1200-01. In *Checkbook*, the Court of Appeals for the District of Columbia Circuit held that "the requested data does not serve any FOIA-related public interest in disclosure." 554 F.3d at 1056. Because release of physician-identifiable claims data is not required under FOIA, it is fully protected from release under the Privacy Act, and may not be disclosed without prior written consent of the physician. 5 U.S.C. § 552a(b).

Alley also concerned a FOIA request for physician-identifiable claims data, but *Alley* was governed by a prior federal district court injunction prohibiting the release of this information. *Alley*, 590 F.3d at 1197. In that earlier case, *Fl. Med. Ass'n v. Dep't of Health and Human Servs.*, 479 F. Supp. 1291 (M.D. Fla. 1979) ("*FMA*"), CMS (then known as HCFA), sought to publish the actual amount of Medicare payments to physicians. The Florida Medical Association and the American Medical Association sued to block disclosure, and the district court held that the Privacy Act prohibited the agency's disclosure of the records. *FMA*, 479 F. Supp. at 1306. The court issued a "permanent injunction on behalf of plaintiffs and the recertified class that they represent." *FMA*, 479 F. Supp. at 1311.

In *Alley*, the Department of Health and Human Services strenuously argued to the Eleventh Circuit that *FMA* prohibited it from releasing the exact type of data that CMS now proposes to grant to Qualified Entities:

> The [*FMA*] injunction permanently bars the disclosure of annual Medicare reimbursement amounts, for any years, which would personally and individually identify those providers who were members of the Florida class. As the government pointed out below, disclosure of the requested physician-identifying information, when coupled with previously disclosed procedure data and the publicly available Physician Fee Schedule, would amount to disclosing annual Medicare reimbursement amounts for individually identified providers in contravention of the Florida injunction.

Brief for Federal Appellant at 17 Alley v. United States Dep't of Health and Human Servs., 590 F.3d 1195 (11th Cir. 2009) (No. 08-16914) ("HHS Alley Brief"). The Eleventh Circuit Court of Appeals agreed, holding that "the *FMA* injunction, reasonably construed, covers" physician-identifiable Medicare claims data. *Alley*, 590 F.3d at 1210. CMS has followed this policy with respect to all Medicare physicians.

Section 10332 of the ACA does not disturb these holdings. It does not repeal or amend the Privacy Act. Accordingly, Section 10332 must be read consistently with the Privacy Act. Section 10332 merely requires CMS to release to Qualified Entities "standardized extracts (as determined by the Secretary) of claims data under parts A, B, and D . . . ." CMS is not required to release *all* claims data or data for all types of providers and suppliers. Therefore, because the Privacy Act forbids the disclosure of physician-identifiable claims data, and because the *FMA* injunction bars its release, CMS may not release to a Qualified Entity Medicare data that would permit the Qualified Entity to determine the amount of reimbursement paid to individual physicians. CMS may release this data for Part A providers and non-physician Part B suppliers, but not for physicians. Alternatively, CMS may disclose to Qualified Entities claims data in which physicians are de-identified or payment amounts cannot be derived from public data sources, such as the Medicare physician fee schedule.

We appreciate the opportunity to provide comments regarding this proposed rule. We look forward to continuing dialogue with CMS on these important issues. If you have any questions about our comments, please contact Bob Jasak at bjasak@facs.org or at (202) 672-1508.

Sincerely,

American Academy of Ophthalmology
American Academy of Otolaryngology- Head and Neck Surgery
American Association of Neurological Surgeons
American Association of Orthopedic Surgeons
American College of Osteopathic Surgeons
American College of Surgeons
American Osteopathic Academy of Orthopedics
American Pediatric Surgical Association
American Society of Anesthesiologists
American Society for Cataract and Refractive Surgery
American Society of Colon and Rectal Surgeons
American Society of General Surgeons
American Society for Metabolic and Bariatric Surgery
American Society of Plastic Surgeons
American Society of Transplant Surgeons
American Urogynecologic Society
American Urological Association
Congress of Neurological Surgeons
Society of Gynecologic Oncology
Society of Thoracic Surgeons
Society for Vascular Surgery