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January 29, 2020

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9915-P
P.O. Box 8010
Baltimore, MD 21244-8010

Submitted via www.regulations.gov

RE: Transparency in Coverage (CMS-9915-P)

Dear Administrator Verma:

On behalf of the over 80,000 FACS members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Services' (CMS) Transparency in Coverage proposed rule (CMS-9915-P) published in the *Federal Register* on November 27, 2019.

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. **We recognize that there are a number of barriers that make it difficult for consumers to obtain cost estimates in advance for health care services, and we support CMS' overarching goal of increasing transparency in commercial insurance coverage to equip patients with the price and benefit information they need to evaluate their care options and make informed decisions in consultation with their physicians.** We encourage the Agency to consider the following issues as it sets policies for the disclosure of price and cost-sharing information by private payors.

PROPOSED REQUIREMENTS FOR DISCLOSING COST-SHARING INFORMATION TO PARTICIPANTS, BENEFICIARIES, OR ENROLLEES

Information Required to be Disclosed to Participants, Beneficiaries, or Enrollees

Estimated Cost-Sharing Liability



CMS proposes to require plans and issuers to disclose cost-sharing information for either discrete items or services for which an individual is seeking cost-sharing information, or, if the issuer bundles payment for items or services associated with a treatment or procedure, for a set of items or services included in the bundle. **The ACS agrees with CMS that price disclosure can inform and empower consumers whether they shop for items and services individually or as part of service packages (i.e., individual shoppable services, explicit or implicit items within bundles, or episodes of care), and we believe that out-of-pocket cost, in addition to total cost of care, are important types of price information for patients. Furthermore, we maintain that payors—not physicians—are best suited to share out-of-pocket cost information with consumers.** While a surgeon or other provider may have a reasonable idea of what services are likely to be provided in conjunction with a given surgical procedure, he or she may not know, or have any influence over, who will be furnishing those ancillary services or whether that provider will be in-network for the patient. For that reason, we wish to reiterate that physicians, who are focused first and foremost on providing the best quality of care for their patients, should not be expected or required to inform patients of their out-of-pocket costs.

The Agency solicits comment on whether other types of information are necessary to provide an estimate of cost-sharing liability prior to an individual's receipt of items or services from a provider(s). **To enhance the usability and accuracy of these data, we encourage CMS and payors to utilize the open-source episode grouper maintained by the not-for-profit Patient-Centered Episode System (PACES) Center, which was officially incorporated in 2019, to create a single industry standard for defining clinical episodes of care using current medical record and payment systems and based on consensus across multiple stakeholders including providers, payors, purchasers, and consumers.** We wish to highlight that PACES is the only episode grouper developed with inputs from across all specialties, and it is continuously governed and updated to reflect the care models used today.

Only with standardized logic and specifications for episodes available in the public domain can there be full transparency and a standard framework that interested parties can use to measure cost, set benchmarks, align quality metrics, and optimize value within and across systems. We believe that one open-source episode system is needed to:

- Define clinical episodes of care in a patient-centric manner;
- Better account for relevant services used to manage a patient's care for a condition or treatment;

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- Promote alignment across payors' design and implementation of episode-based payment models as well as provider's assessment of all resources needed to co-manage a patient;
- Enable consistency between payment models, costs of producing care, and performance measurement; and
- Promote the ability to identify true variations in costs and quality and establish comparisons within and across providers.¹

On the road to reaching a health care environment based on value, achieving transparency both in cost and in quality is an indispensable step to allow for accurate comparisons and decision making. However, to achieve transparency, we must first have clarity as to what we are trying to make transparent for comparison—this process requires standards.



In the complex arena of health care delivery, achieving true transparency can be challenging, especially when multiple competing definitions exist amongst stakeholders. Consensus-based, community-developed standards can reduce such complexity and create clarity about how to make comparable information available to patients in a transparent manner. This information allows for apples-to-apples comparisons, driving value-based decision making for patients in consultation with their physicians.

PACES as a price reporting system can increase transparency by setting standards for episodes of care to be considered, and then providing custom reports to meet the needs of various stakeholders, including for patients comparing options for treatment. For example, an episode of care—including services from multiple sites—can be broken out into distinct phases across the timeline of the episode, with mean or median amounts for a single facility being derived and then compared to those of other facilities. An illustration of these concepts for a colectomy episode is shown in Table 1, below.

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¹ PACES Center. (2019). A common standard for the common good. Retrieved from <https://www.pacescenter.org/static/PACES%20202-page%20Summary.pdf>



Table 1. PACES Service and Price Comparisons for Colectomy Episode

Colectomy Services	Column A	Column B	Column C	Column D
	Medicare Prices		Median Provider Prices	
	25 th percentile	75 th percentile	Medicare	Commercial
Preoperative				
Pre-Surgical E/M	\$ 175	\$ 316	\$ 233	\$ 350
Pre-Surgical Imaging/Lab	\$ 218	\$ 202	\$ 201	\$ 543
Pre-Surgical Other	\$ 309	\$ 209	\$ 312	\$ 780
Subtotal	\$ 702	\$ 727	\$ 746	\$ 1,673
Operative Stay				
Facility	\$ 17,384	\$ 22,818	\$ 17,516	\$ 40,286
Operating Clinician	\$ 1,900	\$ 1,725	\$ 1,821	\$ 5,463
Anesthesia	\$ 549	\$ 339	\$ 478	\$ 1,912
Imaging/Lab Prof. Fee	\$ 125	\$ 139	\$ 167	\$ 668
Other Professional	\$ 58	\$ 58	\$ 45	\$ 79
Subtotal	\$ 20,016	\$ 25,079	\$ 20,027	\$ 48,408
Post-Discharge				
Readmissions	\$ 649	\$ 888	\$ 715	\$ 1,573
PAC-SNF/IRF/LTAC	\$ 556	\$ 669	\$ 602	\$ 1,144
Sequelae	\$ 1,402	\$ 1,511	\$ 1,454	\$ 3,490
PAC Other	\$ 2,361	\$ 2,578	\$ 2,494	\$ 4,988
Subtotal	\$ 4,968	\$ 5,646	\$ 5,265	\$ 11,195
TOTAL	\$ 25,686	\$ 31,452	\$ 26,038	\$ 61,276

Service Profiles

Price Differentials

Table 1 outlines price information for the phases of care (i.e., preoperative, operative stay, and post-discharge) and the specific services that are frequently furnished during a colectomy episode. Columns A and B contrast service profiles for two different facilities, one at the 25th percentile and another at the 75th percentile total Medicare spending for colectomy. The substantial disparity in average Medicare spend for colectomy patients in these two facilities reflects differences in the price of services during the preoperative period, the index stay, transition to post-acute care, sequelae or other post-discharge complications, among others. Comparing Columns A and B illustrates the importance of episode price data; whereas some of the prices for specific services (e.g., pre-surgical services, anesthesia) are higher in the 25th percentile facility, the only way to see the full picture of the cost of care is to look at the total price of the colectomy episode service profile, which shows that the overall lower price of the 25th percentile facility is due in part to its lower post-discharge prices.

Columns C and D in Table 1 contrast the differential payment amounts between Medicare and private payors within a third facility at the median (50th percentile) for total Medicare spend for colectomy. Column C shows Medicare spending amounts for the phases of care and related services described previously. Column D illustrates that the price for a colectomy episode for a



patient enrolled in a private insurance plan differs significantly from that for a Medicare beneficiary, as well as from enrollees of other private plans.

To enable informed decision-making, it is important to enable consumers to assess out-of-pocket cost estimates for a given episode in its entirety, not simply the respective prices for individual service items such as the surgeon's fee, a diagnostic test, or a hospital stay. Columns A and B portray the underlying cost and utilization profiles associated with different facilities, which offer consumers a more transparent and complete overview of the options available to them when selecting among a pool of competing providers. Consumers would evaluate such options through the lens of his or her insurance plan, as depicted in Columns C and D. For consumers with private insurance, providing a comparison or range of estimates of how much patients like them had paid for their entire course of treatment would be valuable in addition the expected out-of-pocket price for a given service—the PACES grouper is capable of producing such an estimate when paired with information from payors. We refer CMS to the comment letter on this proposed rule submitted by PACES for additional details about how such logic could be implemented by the Agency and private payors.

Estimating the actual cost to consumers also typically requires information specific to a patient's insurance coverage, such as their benefits package, deductible, coinsurance responsibilities, and so forth. Thus, the service profile framework could be expanded more generally to inform data exchanges between payors, providers, and consumers. For example, CMS could leverage its partnership with the Da Vinci Project, an industry-led initiative to identify and implement care delivery use cases for the exchange of information between health plans and providers, to participate in the development of patient cost transparency and value-based care data exchange solutions, to advance the Agency's mission to standardize hospital charge information.² Under such a model, a facility or provider could query the insurance plan about a particular patient's benefit design to receive an estimated range of out-of-pocket costs for patients who share the given episode and associated comorbidities—in other words, a patient pool with limited comorbidities will have a very different price profile for the same procedure in a frail patient. Similarly, consumers could use a price calculator on their insurers' websites to query their own plans about differential prices from local providers based on the standard taxonomy for service profiles as clinically meaningful units of pricing.

² Health Level Seven International. (2019). Da Vinci Project members. Retrieved from <http://www.hl7.org/about/davinci/members.cfm>

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Notice of Prerequisites to Coverage

The Agency proposes to require plans and issuers to provide a notice, whenever applicable, informing an individual that a specific covered item or service for which the individual requests cost-sharing information may be subject to a prerequisite for coverage. CMS proposes to define the term “prerequisite” to mean certain requirements relating to medical management techniques for covered items and services that must be satisfied before a plan or issuer will cover the item or service. Specifically, prerequisites would include concurrent review, prior authorization, and step-therapy or fail-first protocols.

Over the past several years, the ACS has urged insurers to make utilization management requirements available online or in electronic health records (EHRs) before or at the point of care in order to give patients and providers the real-time coverage information they need when making treatment decisions. We support CMS’ proposal to require payors to notify enrollees about any prerequisites to coverage in a timely manner.

Disclosure Notice

CMS proposes to require plans and issuers to develop a notice that describes in plain language several specific disclosures regarding cost-sharing liability estimates. The Agency requests comment on its proposed notice disclaimers and whether any additional disclaimers would be necessary or beneficial to consumers’ learning about their potential cost-sharing liability for covered items and services.

The ACS appreciates CMS’ proposal to require plans and issuers to produce consumer-friendly resources to assist enrollees in deciphering their out-of-pocket responsibilities. In particular, we recommend that the Agency revise its proposed disclaimer stating that “actual charges for covered items and services may be different from those described in a cost-sharing liability estimate” to include examples of circumstances under which a patient’s actual cost-sharing liability may differ from the estimate provided by their plan or issuer (e.g., comorbidities, unanticipated complications). **We believe that a more comprehensive explanation of how patient characteristics might affect charges for covered items and services would help enrollees better understand their potential exposure to higher cost-sharing amounts.**

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Required Methods for Disclosing Information to Participants, Beneficiaries, or Enrollees

Internet-Based Self-Service Tool

CMS proposes to require payors to make available an online self-service tool for enrollees to use to search for cost-sharing information for covered items and services. Such tool would be required to: (1) allow users to search for cost-sharing information for a covered item or service provided by a specific in-network provider, or by all in-network providers; (2) allow users to search for the out-of-network allowed amount for a covered item or service provided by out-of-network providers; and (3) provide users real-time responses that are based on cost-sharing information that is accurate at the time of the request. The tool must also allow users to search for cost-sharing information by billing code, facility, and specific quantity and dosage of a prescribed item or service.

The Agency seeks comment on whether this tool should include additional refining and reordering functionalities. **We believe that, to enhance the accuracy of the tool and better account for fluctuations in cost-sharing amounts, CMS should require that it be configured to allow users to self-select health characteristics (e.g., chronic conditions, body mass index) in order to further personalize its outputs for consumers.** The ACS recommends that payors be given flexibility to dictate the specific health characteristics to be included in their tools based on their patient populations, the types of products that they offer, and other elements that might cause cost-sharing estimates to fluctuate. **We also urge the Agency to require that the tool allow users to refine their searches by the subspecialties and quality ratings of providers.**

REQUEST FOR INFORMATION (RFI): DISCLOSURE OF PRICING INFORMATION THROUGH A STANDARDS-BASED API

CMS requested feedback on if pricing information should be made available using standards-based Application Programming Interfaces (APIs). The College is a strong proponent of API technology and supported the Office of the National Coordinator for Health Information Technology's (ONC) proposed 21st Century Cures rule that mandated the use of Fast Healthcare Interoperability Resources (FHIR)-based APIs as the mechanism to share and exchange health data. The College also supports the use of FHIR-based APIs as the standard for sharing and making price information accessible to consumers. API technology is essential for achieving more scalable and efficient interoperability and will further help to ensure uniformity for API users (e.g., patients and enrollees) when attempting to integrate applications.

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Overall, the widespread use of APIs that conform to standards will help to minimize the current hodge-podge of non-scalable technology and help to remove some of the obstacles that currently stand in the way of interoperability and integration.

Setting FHIR-based APIs as the standard for price data will allow for the integration of this data with other third-party health applications and will further allow for these data to be updated in real time, ensuring data available to consumers is accurate and current. As CMS stated in the proposed rule, “health care consumers [could] use a third-party application of their choice to obtain personalized, actionable health care service price estimates, rather than being required to use a specific application or online tool developed or identified by their plan or issuer.” Requiring the use of APIs will better allow for this type of flexibility and will also make the display of the price information consumer- and patient-friendly, better empowering patients to make informed decisions. Developing price-sharing tools using FHIR-based APIs creates the possibility for future integration, collaboration, and innovation across the sector, as well as ensures greater consistency and usability of health technology products.

RFI: PROVIDER QUALITY MEASUREMENT AND REPORTING IN THE PRIVATE HEALTH INSURANCE MARKET

In the *Provider Quality Measurement and Reporting in the Private Health Insurance Market RFI*, CMS discusses the importance of providing quality information in addition to cost information. The ACS believes it is of utmost importance to measure cost alongside quality for a specific condition or episode and that value-based payment (VBP) models should reward those who are able to keep prices down (costs) only if they do so while maintaining or ideally improving the quality of care, defined by health outcomes that matter to patients. Payors must assure that patients are not denied access to appropriate care in order to reduce expenditures. Particularly in value-based payment models which bundle multiple services together to establish a patient outcome with a monetary incentive, it is possible to limit access to unnecessary care. In the course of case management, it is also possible to limit access to essential care. Therefore, in order to assess true quality, payors should first define the condition or episode under consideration for bundling in a value expression. Once the condition/episode is defined, its entire care pathway and all the services needed to assure high quality care must be established. Payors then must seek to assess that quality is not decreased, that the patient’s disease burden is reduced or remains stable, and that care aligns with patient goals.

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Delivery systems armed with information on cost and price, along with meaningful patient-centric quality measures, will be able to more confidently and effectively redesign care models to deliver the same or, preferably, better outcomes with a lower-cost mix of resources, including personnel, equipment, devices, and drugs. This information provides valuable insights for healthcare reform—for those in a fee-for-service environment and for those who may wish to improve efficiency in an accountable care organization (ACO) or take on risk in a bundled payment arrangement.

Current Gaps: Quality Must be Patient-centric with Public Assurance for Optimal Care

CMS solicits feedback on whether there are gaps in current measures and reporting as it relates to health care services and items in the individual and group markets. The ACS believes that the current healthcare system-wide measurement of surgical care is not currently aligned with a patient's experience of care or goals, and there is little transparency for what care will cost them. Most of the measure sets supported by CMS are *ad hoc* and largely still based on billable services. In contrast to the status quo, we strongly assert that quality is not just a “measure,” as it is often defined. Quality is a program which involves a culture of excellence, systems engineering for efficiency, appropriateness, proper resources in structure and processes, and measures for conformance and for outcomes. It integrates data and improvement cycles. In order to assure quality, the ACS' experience is that this comes from setting standards for care (not just for facilities) and assuring, with rigor, that those standards are implemented. This comes from a verification program – such as the ACS Quality Verification Program (QVP) or the ACS Geriatric Surgery Verification (GSV).

We also believe that value is an assessment or judgment that is made by the patient, and therefore, must measure health outcomes that matter to the patient. In order to do this, the quality enterprise should do a better job of ensuring a higher level of measure integrity in a more strategic way, which fit the quality improvement goals of patients within current clinical care models. Payors and the clinical community should set specific quality goals for an episode of care or condition and implement measures which can track to an impact on patient expectations and outcomes and supplement with cost information for that episode or condition. To do this, ACS supports a model that includes verification programs as the foundation for a quality program (such as the ACS Quality Verification Program (SQVP) or similar program), clinical outcome measures, and patient-reported outcomes (PROs) to distinguish performance of surgical teams. These measures should be standardized across plans:

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1. **Verification Programs as the Foundation for Measuring Surgical Quality.** Led by the concept that quality is a program, not just a set of measures, ACS strongly recommends that surgical verification programs, such as the ACS Surgical QVP or the ACS GSV, provide the foundation for assessing surgical quality. These programs use high value process measures to verify that clinical teams have the appropriate resources to deliver optimal care. Having verification as the center of a value-based care program will result in a carefully designed quality program built on evidence-based standards. Components critical to a quality program can be expressed as a cohesive system, including proper structure and process within systems for human factors/systems engineering and data management for reliably tracking outcomes as part of an improvement cycle. The inclusion of a verification program will create public assurances for the achievement of optimal care. It will also provide a business case when closely linked with the revenue models for hospitals and delivery systems. Hospitals and systems have limited experience with the importance of systems engineering quality as a program at the clinical care model level and will require business incentives to generate interest in adoption of comprehensive quality (verification) programs. ACS verification programs have demonstrated improvement in patient outcomes.^{3,4,5}
2. **Clinical Outcome Measures at the Group Level to Monitor High Risk Events.** Clinical outcome measures should be used to monitor high risk events related to preventable harms (i.e., “do no harm”). Attribution at the individual clinician level via the NPI will hardly yield usable performance discrimination due to low volumes and large confidence intervals. To best represent outcome measures, CMS should explore the benefits of program level measurement at the sub-TIN level—sub-TIN refers to identifying clinically relevant groups within the TIN for purposes of measuring team-based care. In addition, overall low event rates of poor outcomes limit the utility of using only clinical outcomes measures for accountability. Therefore, the ACS believes they should be given the lower priority in terms of scoring due to minimal variability across surgical teams. Most procedures or conditions have

³Berger, E.R., Wang, C.E., Kaufman, C.S., et al. (2017). National Accreditation Program for Breast Centers Demonstrates Improved Compliance with Post-Mastectomy Radiation Therapy Quality Measure. *Journal of the American College of Surgeons*, 224(3), 236-244.

⁴Nguyen, N.T., Nguyen, B.S., Nguyen, V.Q., et al. (2012) Outcomes of Bariatric Surgery Performed at Accredited vs. Nonaccredited Centers. *Journal of the American College of Surgeons*, 215(4), 467-474.

⁵MacKenzie, E.J., Rivara, F.P., Jurkovich, G.J., et al. (2006). A national evaluation of the effect of trauma-center care on mortality. *New England Journal of Medicine*, 354(4), 366-78.

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low variability and can be measured with claims data. These measures exist in the current CMS Quality Payment Program and the CMS hospital quality reporting programs. For procedures with high variability, data from clinical data registries, such as the ACS National Surgical Quality Improvement Program (NSQIP), should be used to accurately detect differences in surgical outcomes and take advantage of sophisticated risk-adjustment.

3. *Patient-Reported Outcomes (PROs) to Distinguish Performance.*

The ACS strongly believes that value must be determined based on outcomes which accurately discriminate care delivery and that matter to the patient. The fundamental goal and purpose of health care is to create value for patients. Therefore, it is critical to measure the achievement of patient goals with PROs. Additionally, because most clinical performance measures cannot reliably measure differences in care (discussed further below), PROs are valid for differentiating outcomes for a condition or procedure. With an increased focus and investment in PROs where we measure the patient—not the individual provider—much of the measures in the current system will become irrelevant. There will be a shift to focus on whether patient goals were met, which will necessitate transparency, increased accountability, and care coordination.

It is important to further stress that the appropriate level of rigor for quality measurement is needed and this cannot be done at the individual surgeon (NPI) level. The ACS supports sub-TIN level measurement which allows for relevant clinical groupings to reflect the team-based nature of surgical care. In addition, our work has shown that reliability must be determined on a measure-by-measure basis, taking into account event rates for a specific procedure. For example, in a NSQIP study by Hall et al., the sample size needed to achieve good statistical reliability (0.7) for surgical site infection (SSI) for colectomy was 254 cases, and 1,985 cases for mortality.⁶ Outliers could not be identified for mortality. In other words, the ACS has not generally been able to determine statistically relevant differences across average and high performing clinicians on an individual level of measurement. Challenges related to measuring the performance of individual clinicians results in data being heavily skewed towards high performance, thereby decreasing the ability to show variance among physicians.

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⁶ Hall, B., Huffman, K.M., Hamilton, B.H., et al. (2015). Profiling individual surgeon performance using information from a high-quality clinical registry: Opportunities and limitations. *Journal of the American College of Surgeons*, 221(5), 901–913.

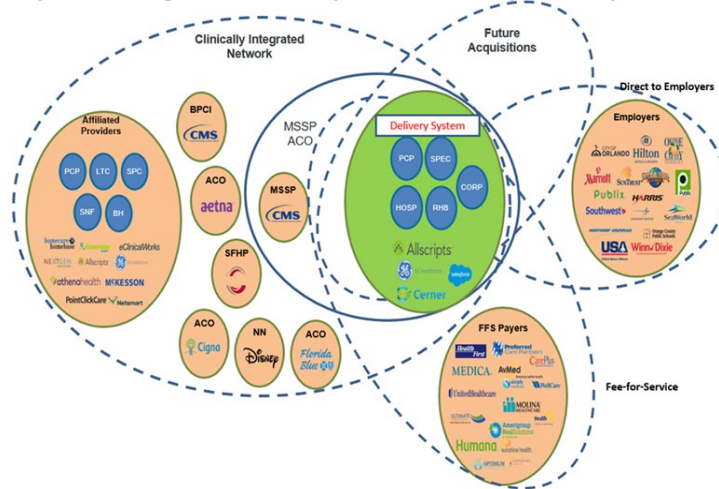


Quality Reporting Should be Standardized Across Plans

CMS solicits feedback on whether healthcare provider quality reporting should be standardized across plans and insurers or if plans should have the flexibility to include provider quality information based on metrics of their choosing. The ACS strongly supports a coordinated effort to get to standardized measurement across all insurers and plans. Figure 1 below provides a snapshot of how complex care has become. We have heard from surgeons that they receive up to ten quality performance rates across different payors—all providing different results. Due to the lack of standards, a lack of rigor, and lack of transparency of quality metrics, surgeons distrust most of the quality information provided to them. Instead of being able to track consistent quality targets with a focus on the patient, they are left to have to figure out how to “pass the test” of each payment program, creating undue administrative burden with little benefit to their patients. Therefore, getting to standards across programs/plans should not be based on metrics of each stakeholder’s choosing. Rather, patients, clinicians, and payors should have a single quality signal that aligns with price information.

Figure 1: 2020 Complex Health Care System Enterprise

Typical Delivery System Reality: Expanding Landscape & Complexity



Digital Services to Support Value-based Care

CMS asks for information on the data sources being used to inform quality metrics. The ACS asserts that interoperability should be thought of as data services which will curate knowledge to inform patients, payors, and the



delivery systems to improve care. The ACS' long-term vision is a patient-centric care model supported by team-based care, rooted in a culture of continuous quality improvement, which can be achieved through advanced digital technology and a standard data infrastructure. Federal support of a vendor-agnostic, open-source patient cloud architecture would shift the industry to a patient-centric system that eases the current burdens with interoperability. The patient cloud aggregates data through a common data model to create a single, unique, and more complete patient medical record, providing physicians with the information they need to deliver the highest quality care while keeping costs low, and gives the patient agency over their own data. The goal is to gain a dashboard of knowledge to drive care decisions for all stakeholders.

Public Reporting of Quality Indicators

CMS discusses the importance of publicly providing quality information and its interest in further promoting competition and transparency. **The ACS believes that in order to best provide this signal to clinicians and patients, public reporting to express value with quality and cost measurement requires more research.** As discussed, the College believes that value is determined by an assessment that is made by the patient and, therefore, must measure health outcomes that matter to the patient. Patients need information on care and outcomes that can be assessed, rather than a single score that represents the way in which CMS or another payor defines value. **Patients value aspects of care differently, and need information on multiple, meaningful, areas from which they can determine value as they define it.** To align with our recommendations for measuring surgical quality, publicly reported information should include participation in a surgical verification program(s) for assurances in quality and safety, actionable cost measures, conformance measures, and PROs. Information from these components will provide patients with meaningful information through which they can assess and determine value. For example, Figure 2 is an example of a radar plot which defines the various elements of care that may be of interest to patients to assess value. These representations are for illustrative purposes only and must be tested for their ability to help patients assess value. Public education programs for learning to interpret value expressions are also essential.

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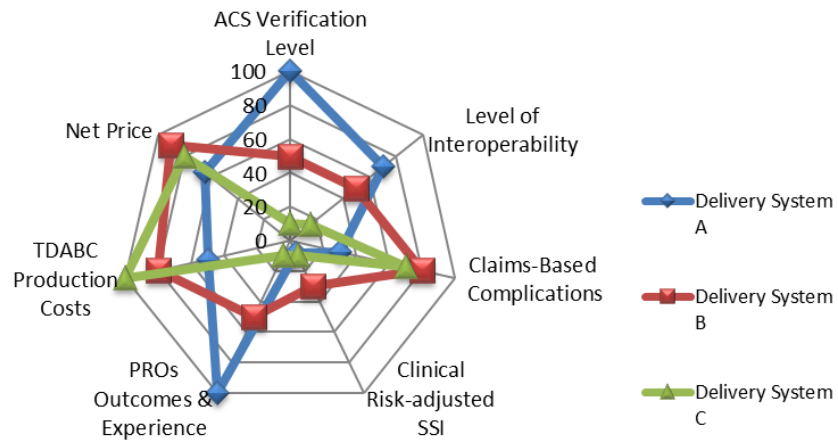
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Figure 2: Sample Radar Chart Episode Value Expression



The ACS appreciates the opportunity to provide feedback on this proposed rule and looks forward to continuing dialogue with CMS on these important issues. If you have any questions about our comments, please contact Vinita Mujumdar, Regulatory Affairs Manager, at vmujumdar@facs.org, or Jill Sage, Quality Affairs Manager, at jsage@facs.org.

Sincerely,

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