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November 20, 2019

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Centers for Medicare & Medicaid Services  
200 Independence Ave. SW  
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Alec Alexander  
Deputy Administrator & Director  
Center for Program Integrity  
7500 Security Blvd.  
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RE: Request for Information on the Future of Program Integrity

Dear Administrator Verma and Mr. Alexander:

On behalf of the over 80,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Services' (CMS) request for information (RFI) on the future of program integrity.

The ACS—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—supports policies that optimize the delivery of surgical services, lower costs, and make the U.S. healthcare system more effective and accessible. We thank CMS for engaging the physician community in its efforts to improve its program integrity tools, and we urge the Agency to utilize the information obtained through this RFI to proactively address vulnerabilities within current processes aimed at ensuring proper payments. The College offers feedback below for consideration as CMS explores various mechanisms for combating fraud, waste, and abuse in the Medicare program.

### PROGRAM INTEGRITY FOR VALUE-BASED PAYMENT PROGRAMS

In the introduction to this RFI, CMS notes the need to ensure continued access to appropriate and necessary care in value-based payment (VBP) arrangements, *“while concerns about overutilization may diminish, new payment models may raise new concerns regarding underuse, also known as ‘stinting.’ In addition, as CMS moves towards more capitated and bundled payments, it may require new approaches to conduct program integrity activities – such as data to evaluate coverage and the appropriateness of care, and monitor other factors, such as beneficiary attribution.”* CMS seeks information on new approaches to address these concerns. The Agency explains that this may include the use of advanced analytics, the reporting of alternative (e.g., non claims-based) data, or other

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mechanisms to identify improper payments, beneficiary safety issues, and other program integrity related concerns.

The ACS agrees with the need to ensure that all patients have access to high value care along with the importance of rethinking how we monitor program integrity during the transition from a fee-for-service payment model toward VBP models. Much of the focus from the Office of the Actuary on this transition is predicated on value-based price (cost). Program integrity must assure that such a monetary focus at least maintains quality as a minimum, and that patients are not denied access to appropriate care in order to reduce expenditures. Thus, we share the need for program integrity efforts to take a patient-centric perspective to preserve CMS' intent for true value in care. 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.

In the transition from fee-for-service (FFS) to value-based care, CMS wisely raises stinting as a key concern for maintaining program integrity. To prevent stinting, CMS must move beyond only monitoring conditions or diseases based on expenditures. CMS must add quality assessment, particularly access to appropriate care, to its plan for how to conduct program integrity efforts within these new payment models. When a payment model bundles multiple services together to establish a patient outcome, and incentives have a monetary component, it is possible to limit access to unnecessary care. However, in the course of case management, it is also possible to limit access to essential care. In order to add true quality to the assessment, CMS must first define the condition or disease under consideration for bundling in a value expression and a new payment model. Once the condition is defined, its entire care pathway and all the services needed to assure high quality care must be established. CMS must seek to assess that quality is not decreased and that the patient's disease burden is reduced or remains stable.

Bundling or grouper software exists within CMS which would define an episode of care and portray the typical services associated with a particular episode. CMS could consider the assessment provided as a first step in serving as a proxy for appropriateness of care by noting variation in care and adding in assessments for patient harms and patient outcomes. These early assessments would assure patients have access to vital care without stinting. It may also serve CMS well to work with specialty societies to define common or typical care pathways using business notations which define case management for an episode of care.<sup>1</sup> Only by understanding the patient's journey, tracking their expectations, satisfaction,

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<sup>1</sup> Object Management Group. (2019). Common Meta-Model and Notation for Modeling. *Case Management Model and Notation*. Retrieved from <https://omg.org/emmn/index.htm>



and patient reported outcomes (PROs) for timely services, can CMS get a sense of how value-based payments are affecting care.

Program integrity efforts must be aware of variation in outcomes and match these to the level of services provided. The cause of variation must not cross thresholds for increasing disease burden or causing additional harms. Therefore, it is important to track patient outcomes and appropriate clinical services within expected pathways, then link outcomes to known factors which influence quality-adjusted life-years (QALY) or disability-adjusted life-years (DALY). Multiple confounding factors are essential when thinking about the value of QALY and DALY in population assessments, including age, gender, and factors such as social determinants of health. When considering age, for instance, within the context of QALY and DALY, CMS would have to match the right outcome with the right condition for the right age. For example, in newborns, CMS would monitor preventable infections, dehydration, and proper nutrition; at ages 50-60, the conditions of concern might be heart disease, diabetes mellitus (DM), chronic heart failure (CHF) and cancer; for women ages 20-35, maternity care might be the focus.

One means of considering how to map and track a particular disease or condition requires CMS to work with specialty subject matter experts to map the clinical pathway (or supply chain) to determine clinically appropriate expected journey(s) a patient will likely travel for a given condition or disease. To do this, CMS can partner with specialties who run risk-adjusted and nationally validated guidelines and clinical data registries which track PROs and clinical outcomes such as the ACS National Surgical Quality Improvement Program (ACS NSQIP). CMS could also leverage digital services using SMART on Fast Healthcare Interoperability Resources (FHIR) to access patient assessments on demand.

With these data, CMS could make determinations based on efficacy and cost. Efficacy and cost could be brought together in a two-by-two analytic which combines these concepts as an over-simplified expression for value. CMS could interpret low value when it discovers outcomes with low efficacy and low cost; and highly value the high efficacy and low cost pathways (immunizations, for example). CMS may discover the need for more appropriateness research to establish efficacy in areas where there is high cost and still unknown efficacy. In one example, patients who have osteoarthritis could be scored preoperatively to see if they would stand to improve with joint replacement or if it would be more appropriate to treat medically, using such scoring systems as HOOS Jr. (hip disability and osteoarthritis outcome score) and KOOS Jr. (knee injury and osteoarthritis outcome score) along with age, gender, and BMI. The overall intent is to decide on key conditions that assess the relationship of cost and efficacy of treatment and determine the impact of care on QALY/DALY and PROs. Through

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this analysis, CMS would get a sense of the appropriateness care. The suboptimal impact of care may be caused by other factors such as patient co-morbidities or unpreventable harms. CMS would need to establish a distinction that designates when the impact is primarily related to avoidance or poor access to essential care. It is also possible to expose a failure in the payment model for under-valuing costs and constraining care delivery. More research would be needed to further define the causes for any shortfalls and where to attribute those events.

Below is a detailed framework that describes how to assess patient-centric value in surgery as we transition from FFS toward VBP.

### ***VBP Framework for Program Integrity***

In order to achieve a patient-centric quality program in surgery, ACS believes scoring for quality should constitute three categories with shared attribution at the team level, including 1) participation in a verification program, 2) conformance measures applied as appropriate to the right condition/procedure, and 3) PROs based patient surveys that are valid for differentiating outcomes for a condition or procedure. These three categories are described below:

#### **1. Participation in a Verification Program**

Quality measurement should ensure that the proper structures and processes are in place for the provision of high-quality care. To do this, surgical VBP models should be rooted in a surgical verification program, such as the Surgical Quality Verification Program (SQVP).<sup>2</sup> Verification programs pursue excellence and avoid system errors by ensuring that the resources, staff, and infrastructure are in place to provide the highest possible quality care to the patient.

The SQVP is designed as an overarching assessment of a quality program, which can be applied broadly across a delivery system regardless of the practice type (academic, community, or rural care delivery system). In addition to the more broadly applied verification programs, the ACS also has service line-directed programs that more narrowly define quality elements for a particular clinical domain, such as trauma, cancer, metabolic and bariatrics, frail elderly and geriatrics, pediatric surgery, complex GI, and vascular surgical service lines. These programs can also be applied in multiple care settings such as academics, community or rural-based care.

One example of program integrity achieved through verification is demonstrated

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<sup>2</sup> American College of Surgeons. "Optimal Resources for Surgical Quality and Safety." 2017. Retrieved from: <https://www.facs.org/quality-programs/about/optimal-resourcesmanual>



in the dramatic improvement in perioperative mortality for patients undergoing bariatric surgery. The improvement is associated with more than 800 bariatric centers that have been verified through the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP). The program measures the entirety of the patient's care experience and the care team, linking the roles and contributions across the care team to optimize care. MBSAQIP hospital accreditation status is associated with safer outcomes, shorter length of stay (LOS), and lower total charges.<sup>3</sup>

The ACS SQVP standards include several quality-related domains applicable across surgical specialties which can be used on a broader scale:

1. Institutional administrative commitment
2. Episode program and scope
3. Facilities and equipment resources
4. Personnel and services resources
5. Patient care: expectations and protocols
6. Data systems and surveillance
7. Quality improvement
8. Research: basic and clinical trials
9. Education: professional and community outreach

## 2. Track Conformance Measures

In addition to verification, it is critical to track conformance quality. Conformance quality includes clinical standards and monitoring high risk events related to preventable harms (i.e., “do no harm”), such as Surgical Site Infection (SSI), Readmissions and Surgical Risk Calculator, etc. Standards in verification programs include data systems that track conformance measures that are actionable and allow for the focus to shift to measuring the achievement of patient goals of care.

## 3. Include PROs Appropriate for the Patient's Condition/Procedure

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 is a proxy for value. Patients value aspects of care differently, and need information on multiple, meaningful, areas from which they can determine value as *they* define it. Information from these three components will

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<sup>3</sup> Morton, J.M., Garg, T., & Nguyen N. (2014). Does hospital accreditation impact bariatric surgery safety? *Annals of Surgery*, 260(3), 504-508; discussion 508-509.



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provide patients with meaningful information through which they can assess and determine value.

ACS is currently working on a project with the Harvard Business School (HBS) Institute for Strategy and Competitiveness which will include verification, conformance and performance measures to define quality. The ACS THRIVE (Transforming Health Care Resources to Increase Value & Efficiency) initiative is designed to help hospitals and surgical practices improve patient outcomes while lowering the cost of delivering care as reimbursement shifts to bundled payments—an approach that increases transparency and accountability. This newly designed value-measurement process will be piloted at 10–15 U.S. hospitals, focusing on measuring the full cycle of care—including its key surgical, medical, behavioral, and social elements—for three surgical conditions. For more information on this project please visit, <https://www.facs.org/quality-programs/acs-thrive>.

### ***High Measurement Rigor for Program Integrity***

Proper risk adjustment is also necessary to ensure program integrity when differentiating one care provider from another. As payments are increasingly attributed to care in VBP, it has never been more important to prevent the misclassification of care. The ACS has stressed the importance of a “single source” or entity to aggregate data for benchmarking performance. In our experience with NSQIP and other ACS clinical data registries, we have demonstrated that it is critical for measures to be analyzed and aggregated by a single source for consistency in data interpretation, including standardized data definitions, standardized risk adjustment/data analytics, consistency of data ascertainment methods, and common normalization methods. It is otherwise virtually impossible (and overly costly) to create reliable and valid comparisons between care systems when multiple data aggregation systems are used for measurement. It is also critical to use the appropriate measure science when determining validity and reliability. For example, the current Merit-based Incentive Payment System (MIPS) program requires a percentage of cases over a 12-month period to determine performance for a given quality measure. This is arbitrary and has no basis in measure science, resulting in inconsistent levels of statistical power when comparing clinicians. We have proven that the data completeness requirement is not reliable for most surgical measures as a result of the number of cases a surgeon completes in a 12-month period—this is the case

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for clinical outcome measures that monitor low event rates such as mortality and SSI in particular.<sup>4</sup>

## PRIOR AUTHORIZATION IN MEDICARE FEE-FOR-SERVICE

CMS seeks feedback on the potential for prior authorization (PA) to be improved under Medicare FFS. PA is an inefficient and onerous requirement for surgeons, and the ACS is deeply concerned that the continued introduction of such processes into the Medicare FFS program will inappropriately delay patient care and unduly restrain physicians who adhere to clinical standards and evidence-based medicine. The extensive PA requirements currently imposed by private payors—including Medicare Advantage organizations (MAOs)—already place an extraordinary administrative burden on physicians and their practices, and we believe that such payors routinely and increasingly use PA to deter physicians from ordering or furnishing medically necessary treatment for patients, rather than as a legitimate mechanism for identifying overutilization. While we recognize that utilization review tools such as PA can sometimes play a role in ensuring that patients receive clinically appropriate treatment while controlling costs, many of these requirements are applied to services performed in accordance with an already-approved plan of care. Additionally, even if a physician is granted authorization for a service, payors may deny or retrospectively collect payment for services for which PA was obtained. As payors continue to subject a growing number of services to PA, physicians can no longer afford the increased practice costs related to compliance with PA requirements and are left with no option but to leave plan networks. When a physician becomes out-of-network, patients must either seek care elsewhere or pay out-of-pocket, both of which inappropriately delay care and shift costs onto patients.

**The College strongly believes that CMS intervention in this area is urgent and necessary in order to decrease the overwhelming administrative burden of PA requirements and to maintain beneficiary access to a broad range of services under Medicare FFS.**

We ask that CMS address the numerous process flaws associated with PA through the following actions:

- **Selective application of PA.** CMS should limit the scope of PA requirements to physicians whose ordering practices stray from evidence-based medicine or suggest a pattern of overutilization (after

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<sup>4</sup> Hall BL, Huffman KM, Hamilton BH, Paruch JL, Zhou L, Richards KE, Cohen ME, Ko CY. Profiling individual surgeon performance using information from a high-quality clinical registry: Opportunities and limitations. *JACS*. 2015;221(5):901–913. Retrieved from: <https://www.ncbi.nlm.nih.gov/pubmed/26363711>.



adjusting for patient population). PA should not be applied to services that are typical for a specific condition, are part of an ongoing therapy regimen, exhibit low variation in utilization or denial rates, or have been approved previously as part of a patient's care plan.

- **Elimination of trivial barriers to payment.** Payment for services for which PA was granted should not be later denied based on billing technicalities. For example, reimbursement should not be withheld when the service performed is clinically comparable to an approved service but is more properly reported using a different American Medical Association Current Procedural Terminology (CPT) code or when a procedure's necessity was not anticipated, or the procedure is performed incident to, or during the course of, an approved operation.
- **Data collection.** Reasonable resolution of physician and patient grievances with respect to PA requires comprehensive and specific information regarding the Agency's PA processes and outcomes. Therefore, CMS should report on the extent of its use of PA and the approval/denial rate by service. This should include the submission of data on the specific procedures subject to PA; the proportion of each service approved; and the time elapsed from submission until the issuance of an organization determination.
- **Alignment with industry standards.** We urge CMS to follow the set of PA principles endorsed in January 2018 by associations representing managed care plans, including America's Health Insurance Plans (AHIP) and Blue Cross Blue Shield Association (BCBSA).<sup>5</sup> Such principles identified areas that "offer opportunities for improvement in prior authorization programs and processes that, once implemented, can achieve meaningful reform." These include, among others, an annual review of services subject to PA and the removal of services from PA lists for which PA is unnecessary; protections for continuity of care for patients on appropriate, stable therapy; and the industry-wide adoption of automated PA processes.

PA burden is further exacerbated by the lack of a uniform format for the submission of PA information. We appreciate that CMS recently proposed Part D e-prescribing regulations to require Part D plans sponsors' support

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<sup>5</sup> American Medical Association. (2018). Consensus Statement on Improving the Prior Authorization Process. Retrieved from: <https://www.ama-assn.org/sites/default/files/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf>





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of the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard (version 2017071) for use in electronic PA transactions with prescribers for Part D covered drugs.<sup>6</sup> In addition, we thank CMS for finalizing requirements for Part D plan sponsors to adopt one or more Real-Time Benefit Tools (RTBTs) that are capable of integrating with at least one prescriber's e-prescribing system or electronic health record (EHR) by 2021.<sup>7</sup> To facilitate similar uniformity for *medical* services, we urge CMS to require adoption of ASC X12 278 and issue model PA forms. We also ask that PA requirements be made available online or in EHRs at the point of care to provide physicians with the real-time coverage information they need when making treatment decisions in collaboration with their patients.

We further commend CMS for its efforts in its *Advance Notice of Methodological Changes for Calendar Year 2020 for Medicare Advantage Capitation Rates, Part C and Part D Payment Policies and 2020 Draft Call Letter* to prompt all payors, including MA plans, to align their PA processes with recommendations made under 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. CMS noted in the draft call letter that, in support of the Da Vinci Project, it began developing a prototype Medicare FFS Documentation Requirement Lookup Service (DRLS), which would digitally utilize the information inserted by a physician into their EHRs for a specific Medicare FFS beneficiary to determine what (if any) documentation or PA requirements might impact clinical decision-making or coverage for that patient with respect to certain durable medical equipment (DME); if the DRLS identifies any such requirements for the applicable items, it would automatically respond to the physician through their EHR with the appropriate documentation or PA policies as well as any related templates the physician should complete and include to CMS in their claims submission. The Agency recommended that payors develop a similar lookup service and populate the tool with their documentation rules and list of items and services for which PA is required.

**The ACS supported CMS' message to payors in the draft call letter and agrees that patient and payor data should be leveraged in EHRs to notify physicians of PA and other documentation requirements when ordering a service; further, we believe that any such integrated solutions should automate PA decisions for routine therapies and pre-**

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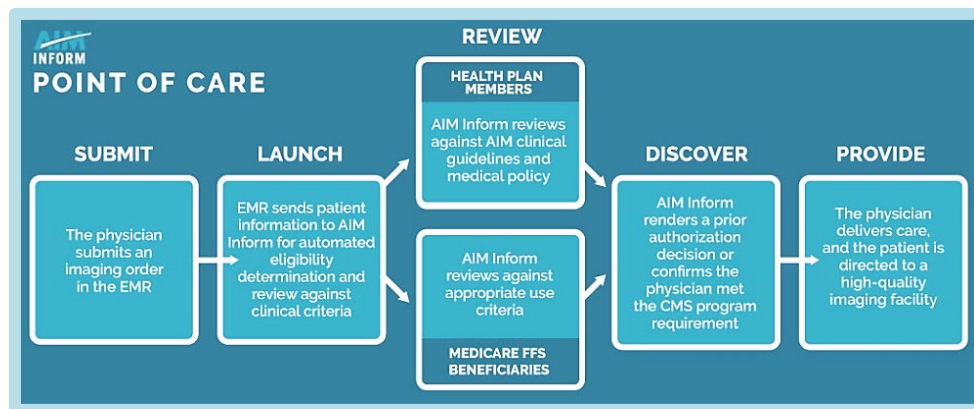
<sup>6</sup> 84 FR 28450

<sup>7</sup> 84 FR 23832



populate PA forms for cases in which further review is needed. The use of information already stored in EHRs to complete such processes could streamline payor-provider communication, improve the accuracy and efficiency of these administrative tasks, and ensure the timely provision of care. As CMS tests and refines its DRLS prototype, we encourage the Agency to obtain additional expert guidance from organizations already experienced in the development of health information technology (HIT)-enabled PA; AIM Specialty Health's AIM Inform tool, which eliminates the need for physicians to use separate technologies to fulfill PA and other CMS billing requirements, is one such example of an effective model to unify multiple components of the clinical workflow (see Figure 5).<sup>8</sup>

Figure 5. AIM Inform Logic Model



To improve existing PA processes and related technologies, we recommend that the Agency incorporate three major elements into its execution of PA to ensure scientific rigor and appropriate reimbursement within Medicare FFS: (1) base PA logic on current evidence from appropriate clinical experts and publish such logic as an open standard with a public comment period; (2) facilitate the development and utilization of clinical decision support tools using FHIR-based application programming interfaces (APIs) for the purposes of digitizing and automating PA within EHRs; and (3) encourage all health plans to use the same open standards and electronic services for PA in order to avoid both the imposition of different PA logic from each payor, as well as confusion related to compliance with multiple plans' PA requirements in the clinical setting.

<sup>8</sup> AIM Specialty Health. (2018). Payment Clarity at the Point of Care. *AIM Inform*. Retrieved from <https://www.aimspecialtyhealth.com/Solution-AIMInform.html>



## PROVIDER EDUCATION

CMS seeks feedback on provider education. Specifically, the Agency asks for input on existing strategies, tools, or technologies that could help providers and suppliers become more aware of necessary documentation requirements earlier in the claims process, as well as to better connect ordering physicians, rendering providers, and suppliers with respect to their responsibility to submit proper documentation.

### Electronic Health Records and Data Systems

The College commends CMS' commitment to improving HIT to empower patients. We agree that EHRs are unable to provide the functionality and capabilities needed to bring healthcare into the twenty-first century, and to put data back into the hands of patients and physicians to facilitate the improvement of high value care and ease administrative burdens. The MyHealthEData initiative is an important step in the transformation of HIT, and toward making health data both easily accessed and shared. The College recommends working with the Office of the National Coordinator for Health Information Technology (ONC) to ensure that national standards, such as FHIR-based APIs, are the foundation for solutions that allow for the exchange of health data between physicians, patients, and systems, creating more accurate and complete documentation.

To move beyond EHRs and achieve CMS' goal of easily accessed and shared health data, the industry must begin the shift to a **semantically interoperable, digital information system as a service in a patient cloud**. The patient cloud aggregates data to create a single, unique, and more complete patient medical record, providing physicians with the information they need to deliver high value care, including robust quality data and a better understanding for the cost of patient care, while giving the patient agency over their own data. EHRs will remain a key point of data entry at a care site but need to connect to cloud platforms to share clinical information, expand data liquidity, and make patient health information more accessible by both patients and clinicians. In addition, consideration should be given to structured data capture using tools like Smart on FHIR and FHIR Questionnaires to capture episode-specific data.<sup>9,10</sup>

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<sup>9</sup> SMART on FHIR. (2017). *SMART: Tech Stack for Health Apps*. Retrieved from <https://docs.smarthealthit.org>

<sup>10</sup> HL7. (2019). *Resource Questionnaire – Content*. Retrieved from <https://www.hl7.org/fhir/questionnaire.html>



Patients have data in multiple EHRs, third-party applications, wearable devices, and payor claims; there is no current, single source of truth for aggregated health data. By moving to a patient cloud platform, not only will there be a single, aggregated source of clinical data, but it will also allow for quality measures to be analyzed and aggregated within a single source, creating consistency in data interpretation and increasing statistical rigor when measuring quality across hospitals and systems. This will enable the use of standardized data definitions, standardized risk adjustment and data analysis, consistency of data ascertainment methods, and common normalization methods.

The next generation of digital health services must create a single, unified patient record in a cloud platform. Using a Linux-like architecture for an open-standard cloud architecture will create a patient unified record upon which *all* EHRs can provide data, all smartphones can interact, and all API developers can drop in services for patients and clinicians.<sup>11</sup> The patient cloud would work as an aggregator, able to pull data through APIs from any database with patient information, and then process, convert, and exchange data as appropriate. With shared standards, any digital information company can apply the standard and create a semantically interoperable cloud. The free market can then employ these standards and avoid overbearing, inefficient, and costly duplicative services. Digital services like third-party applications and wearable devices can also build upon these clouds to further accelerate the advancement of the industry.

In order to achieve CMS' vision of using Artificial Intelligence (AI)/Machine Learning (ML) to ease documentation burden for providers and ensure more accurate and appropriate data on Medicare Claims, the above platform is foundational. This advanced model of interoperability using a patient cloud allows for the digital transformation of data into knowledge and insights, as it is able to take in huge amounts of data, process it, display it, and share it with a variety of different endpoints and systems, for a variety of different purposes, ranging from care to payment. Further, these technologies could provide opportunities to guide physicians through semantically-interoperable care models and use natural language processing (NLP) to pull context from free-text notes and other areas of the patient record, creating the discrete data points needed for billing. This model allows for the advanced use and integration of digital tools, as well as the flexibility to advance alongside future technological developments.

### Provider Directories

Maintaining up-to-date information about provider participation in health plan networks is a challenge for payors across the country. Consumers

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<sup>11</sup> Linux. (2019). *What is Linux?* Retrieved from <https://www.linux.com/what-is-linux>





increasingly rely on online provider directories to review networks when choosing a plan, but many payors, including MAOs, have failed to offer directories that accurately reflect the providers available through their networks, their capabilities and qualifications, and the availability of such providers to new patients. In order for consumers to be able to make informed decisions about their medical care, it is critical that payors and providers ensure that their directories are valid.

Currently, CMS requires MAOs to post on their websites their network of contracted providers (including the names, addresses, phone numbers, and specialties of such providers).<sup>12</sup> MAOs must maintain accurate online provider directories that list only actively contracted providers with specific notations for those who are not accepting new patients. In the event that a change is made to an MAO's network, the organization must make a good faith effort to provide written notice of a termination of a contracted provider at least 30 days before the termination effective date to all enrollees who are patients seen on a regular basis by that provider; when a contract termination involves a primary care physician, all enrollees who are patients of that provider must be notified. In 2018, CMS completed its third annual review of MAOs' online provider directories, the results of which demonstrated a lack of improvement in the accuracy of provider directories over the past three years.<sup>13</sup>

**The ACS believes it is imperative that payors' network listings are up-to-date, correct, and easy for patients to access, and we encourage CMS to strengthen its oversight and enforcement mechanisms to ensure that MAOs achieve acceptable levels of directory accuracy.**

Efforts to address coverage issues related to whether providers are in- or out-of-network will only be successful if there is sufficient transparency and accessibility of information as to a provider's network status.

However, we recognize that the current process of verifying the accuracy of provider information presents an undue burden on providers, as they must complete the same set of validation questions for each of the multiple MA plans they contract with. **To make directory data collection and verification more efficient for providers, we urge the Agency to utilize the provider data it collects to determine how it may be used to foster a collaborative industry approach to achieving a centralized location**

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<sup>12</sup> 42 CFR § 422.111

<sup>13</sup> Centers for Medicare & Medicaid Services. (2018). Online Provider Directory Review Report.

Retrieved from: [https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/Provider\\_Directory\\_Review\\_Industry\\_Report\\_Round\\_3\\_11-28-2018.pdf](https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/Provider_Directory_Review_Industry_Report_Round_3_11-28-2018.pdf)



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**for such data.** A centralized database could allow the current inward facing MAO efforts to have a broader impact; for example, when an MAO identifies a directory error, it currently is fixed only for their own directory, whereas a corrected error in a centralized database would improve directory accuracy for all MAOs using that system.

The College also encourages CMS to collaborate with the ONC in its work to create a validated healthcare directory as a way to further reduce administrative burden. Such a directory would include a broad set of provider data that supports a variety of healthcare directory use cases. Data within this directory would be validated against primary sources (e.g., state licensing boards for licensure information) and available to local environments through a national exchange standard. Providers would only be required to attest to the accuracy of much of their information once for the national resource, rather than for each local environment. **Establishing a single repository for payor and provider data would greatly simplify the directory update process and improve the customer experience for patients**—a number of states have already begun developing and testing centralized provider directories (e.g. California’s Symphony Provider Directory) in an effort to streamline how payors and providers exchange and reconcile provider information in compliance with state and federal regulations.

### Certification of Medical Necessity

Medicare documentation policies create significant burden that delays patient care with redundant requirements for verifying physician orders and reviewing voluminous medical records where important patient information is difficult to identify within pages of irrelevant, formulaic language. CMS will only pay for covered services if physicians certify and recertify medically-necessary care and equipment that patients require, including hospital stays, wheelchairs, colostomy supplies, diabetic testing supplies, physical therapy, and home health and hospice services. While CMS relies on these policies based on perceived program integrity benefits, these documentation requirements are repetitious and tedious and require physicians to review lengthy charts to confirm an order that they have already determined to be medically necessary yet do not meaningfully address fraud and abuse risk.

Physicians are expected to provide an excessive amount of information to certify medical necessity, including a written prescription for a service or item with the appropriate International Statistical Classification of Diseases and Related Health Problems (ICD)-10 code, copies of medical notes to prove a patient’s condition, and specification of the reason the

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service or item needs to be rendered. However, in many cases, a prescription and ICD-10 code should be sufficient in certifying the diagnoses, symptoms and procedures a patient received. Even when standardized treatment is prescribed for common services that follow evidence-based protocols, documentation and certification requirements continue to apply. The certification and recertification process is further complicated by the lack of uniformity among documents included in a patient's care plan, which includes numerous pages of redundant and unorganized information that is often difficult for the referring physician to interpret.

**We do not believe that the current certification process leads to a meaningful exchange of information between providers, nor does it offer any benefit to patient care or advance program integrity.** While we believe that it is important for all members of a patient's care team to be aware of and involved in the patient's treatment plan, we do not think that a referring physician is best suited to certify orders that are prescribed by another clinician. For example, under current certification requirements, a general surgeon who referred a patient that underwent a proctopexy for rectal prolapse to a physical therapist (PT) for postoperative care (e.g., biofeedback training) must certify the PT's treatment plan, even though the surgeon may not have the requisite knowledge needed to determine if the number of visits, specific targets of intervention, and other factors of such treatment plan are most appropriate for the patient. Notably, the referring physician's certification is needed for the PT to be paid under Medicare, but that referring physician does not receive reimbursement for the time and effort spent assessing another provider's orders. **The ACS urges CMS to standardize and streamline certification forms and asks that CMS take a more targeted approach in the application of these requirements, such that the furnishing provider—rather than the referring provider—be responsible for certifying their own plan of care.**

### Audits

Physicians are needlessly burdened with exorbitant requests for clinical documentation from CMS and its auditors (including Medicare Administrative Contractors [MACs], Recovery Audit Contractors [RACs], Unified Program Integrity Contractors [UPICs], Quality Improvement Organizations [QIOs], Comprehensive Error Rate Testing [CERT] contractors, Supplemental Medical Review Contractors [SMRCs], and Risk Adjustment Data Validation [RADV]). Compliance with these requests costs practices significant time and money. Pre- and post-

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payment reviews are often voluminous and not completed in a timely manner, which deprives physicians of reimbursement for extended periods of time; this particularly affects small practices that do not have the resources to meet the demands of multiple audits or continue to provide quality care while waiting for payments suspended during the review process. Physicians complying with auditors' requests continue to provide services to patients while awaiting payment for claims that may have been submitted several years ago—this process may also delay payment for recently submitted claims, resulting in a loss of revenue and impeding practices' ability to maintain clinical operations.

The amount of reviews and types of contractors are overwhelming, add unnecessary costs, and distract from the delivery of care. These audits are a great source of frustration and expense, and physicians need a single transparent, consistent, and fair review process to reduce administrative burden. **The ACS urges CMS to develop a standardized approach through which audit contractors notify providers of a review, request medical records, and, where applicable, inform providers of the specific reason why a claim is denied and clearly state a provider's appeal rights.** Given the vast number of reviews that physicians may be subjected to, CMS should clarify the function and authority of each reviewer and develop an online portal detailing the sampling and extrapolation methodologies that each reviewer employs. **Expenditures, such as printing and shipping fees, for providers who receive clinical documentation requests from auditors are high, and we urge CMS to require auditors to reimburse physicians who win on appeal of an audit the full cost of complying with the review process.**

The ACS appreciates the opportunity to provide feedback on this RFI, and we look forward to continuing dialogue with CMS on ways to improve program integrity. If you have any questions about our comments, please contact Vinita Mujumdar, Regulatory Affairs Manager, at [vmujumdar@facs.org](mailto:vmujumdar@facs.org), or Jill Sage, Quality Affairs Manager, at [jsage@facs.org](mailto:jsage@facs.org).

Sincerely,

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