

October 29, 2020

Alexandra Goss
Sheryl Turney
Co-Chairs
Intersection of Clinical and Administrative Data Task Force
Office of the National Coordinator for Health Information Technology

# RE: A Path Towards Further Clinical and Administrative Data Integration Draft Report of the Intersection of Clinical and Administrative Data Task Force

Dear Ms. Goss and Ms. Turney:

The Medical Group Management Association (MGMA) is pleased to submit the following comments in response to the Office of the National Coordinator for Health Information Technology (ONC) Intersection of Clinical and Administrative Data Task Force draft report A Path Towards Further Clinical and Administrative Data Integration. This draft report seeks to move the health care ecosystem in the direction of data integration in an effort to decrease administrative burden and improve care for patients. We commend the Task Force for recognizing the need to improve the integration of clinical and administrative data, especially in the area of prior authorization, and for seeking stakeholder feedback on how this best can be accomplished.

MGMA is the premier association for professionals who lead medical practices. Since 1926, through data, people, insights, and advocacy, MGMA empowers medical group practices to innovate and create meaningful change in healthcare. With a membership of more than 58,000 medical practice administrators, executives, and leaders, MGMA represents more than 12,500 organizations of all sizes, types, structures and specialties that deliver almost half of the healthcare in the United States.

The Task Force has set out an aggressive set of recommendations, many of which we are in full agreement with. In our comments below, we suggest that several of the recommendations would benefit from including additional specificity and we contend that moving the needle on prior authorization will require federal government mandates on health plans. We understand, however, that the primary lever for the federal government in this policy area is with those health plans under federal control (Medicare, Medicaid, Medicare Advantage and MADPs, OPM/FEBP, and DOD/Tricare) and it will be important to first start the improvement process by mandating changes to their policies.

While we support many of the Task Force's observations, including arming patients with the health information they need, we believe the draft report should be modified to ensure that physician practices and other care providers gain quicker access to more accurate and pertinent patient information that directly improves the patient care delivery process. In order to affect an industry-wide transformation of the current prior authorization process, it is critical that commercial health plans be required to modify their current policies and processes. Unfortunately, voluntary recommendations are not likely to result in widescale industry adoption of new processes, especially in the area of prior authorization. This transformation could lead directly to enhanced efficiency and improved clinical performance.

# Summary of Key Comments

- Prior authorization is one of the most onerous administrative requirements facing
  physician practices. MGMA member survey data report that prior authorization
  processes present significant administrative challenges and can negatively impact patient
  care. We appreciate and support the Task Force's focus on prior authorization issues.
- Focus on reducing the overall volume of prior authorizations. The Task Force recommendations do not focus enough on opportunities to reduce the overall volume of prior authorizations. Volumes can be reduced by eliminating the authorization requirement for routine services, for practices in risk contracts, by implementing "gold card" programs for high performing practices, and through other methods.
- Leverage Star Ratings and other government programs to improve prior authorization. The Centers for Medicare & Medicaid Services (CMS) offers a number of programs, including the Star Ratings Program for health plans and the Quality Payment Program for eligible groups and clinicians. These and other agency programs can be leveraged to improve prior authorization processes
- Require health plan transparency. The draft report should include additional commercial
  and federal health plan transparency requirements. All health plans should be required to
  publish metrics on services that are frequently approved, authorization and denial rates,
  rates of appeal, appeals, and other factors.
- Expedite release of the long-overdue electronic attachments standard. We have long
  called on CMS to issue the regulation establishing a national standard for electronic
  attachments. We concur with the Task Force that implementation of this standard will
  significantly streamline the submission of clinical documentation in support of a prior
  authorization.
- Recognize the appropriate role of the patient in the prior authorization workflow. While we agree that having the patient armed with their health information will improve the care delivery process, we oppose having the patient be responsible for conducting prior authorization transactions. This would lead to unintended consequences, including a higher instance of delayed or denied care.
- Permit and incentivize the testing of innovative prior authorization solutions. New standards and new processes are being developed that could streamline the current prior authorization environment. These innovations should be encouraged and finically supported by the federal government.
- **Enforce health plan non-compliance.** We urge the Task Force to recognize that health plan non-compliance with federal regulations is a contributing factor to the administrative burdens experienced by providers.

## **Current Prior Authorization Environment**

Prior authorization continues to be one of the most onerous administrative processes faced by physician practices and we advocate for a reduction in the volume of prior authorization requirements and automation of the remainder. As a cost-control process requiring providers to qualify for payment by obtaining approval before performing a service, prior authorization is overused, costly, inefficient, and can be responsible for delays in patient care.

Documentation requirements from health plans for items and services associated with prior authorization and ordering for certain medical services are also significant sources of administrative burden. Congress and the Administration can play an important role in evaluating and addressing administrative processes and clinical workflow factors contributing to this burden. While electronic health records, practice management system software vendors and other health IT solutions can also play a role in reducing this burden, prior authorization processes suffer from a lack of standardization and common approaches.

Not only are prior authorization requirements challenging, but MGMA members also report that prior authorization requirements from health plans are actually increasing. In a <u>poll</u> conducted September 17, 2019 with almost 1,000 respondents, 90 percent reported that prior authorization requirements had increased in the past year, 9 percent stated that requirements had stayed the same, and one percent indicated they had decreased.

To put prior authorization into perspective and to compare this task with other administrative burdens facing medical practices, the MGMA <u>regulatory burden survey</u> asked practice executives to rate a number of administrative challenges from not burdensome to extremely burdensome. The survey results were released October 14, 2019 and included responses from executives representing over 400 group practices. Two-thirds of respondents are in practices with less than 20 physicians and 14 percent are in practices with over 100 physicians. Three-fourths of respondents are in independent practices.

Survey respondents identified prior authorization as the leading regulatory burden facing their practice in 2019 with fully 83 percent rated prior authorization as either very or extremely burdensome.

#### Prior Authorization Approval Rates and Practice Costs

The utilization of medical services and medications should not significantly increase if prior authorization requirements are relaxed due to the fact that the majority of authorization requests are ultimately approved. On October 28, 2019, MGMA completed a poll of almost 200 physician practice executives asking first the question: Approximately what percentage of prior authorization requests submitted to your health plans are approved during the first submission process?

The mean response rate was 72 percent

We then asked: For prior authorization requests not approved during the first submission process that are subsequently appealed, approximately what percentage are approved by your health plans following the appeal?

The mean response rate was 75 percent

Finally, we asked the respondent: For prior authorizations that require a peer-to-peer (practice clinician to health plan clinician) discussion, approximately what percentage are approved by your health plans?

The mean response rate was 85 percent

Poll respondents reported that the majority of authorization requests are approved by the health plan the first time they are submitted. For those that are appealed by the practice following a denial by the health plan, again, the majority are approved. In those cases where the appeal requires a peer to peer (direct discussion between the practice clinician and a clinician designated by the health plan) consultation, the vast majority of authorizations are approved by the health plan.

This lengthy process results in significant burden for practice administrative and clinical staff. Practice costs related to prior authorization include:

- Clinical and administrative staff time spent determining if an authorization is necessary for a particular service, test, or medication. Each health plan has their own proprietary medical necessity requirements, thus adding additional burden for practice staff. Some practices report they are forced to have staff assigned to specific health plans to conduct prior authorizations;
- Clinical and administrative staff time determining what documentation is required to support the individual plan's medical necessity requirements;
- Administrative staff time transmitting the prior authorization request and support documentation to the health plan (most often via mail, facsimile, or uploaded through a health plan's website);
- Clinical and administrative staff time spent responding to a health plan authorization denial, which may include compiling and transmitting additional clinical documentation; and
- Clinical staff time to engage in a peer-to-peer discussion of the clinical issues.

# Comments on the Draft Report Recommendations

**Recommendation 1**: Prioritize Administrative Efficiency in Relevant Federal Programs

The Task Force recommends that ONC work with CMS and other Federal Agencies to work aligned administrative efficiency objectives into relevant federal payment programs (e.g., HEDIS, MA/MADP STAR ratings, MIPS, MSSP, Promoting Interoperability, etc. and private payers contracting through Tricare and FEHP), and that ONC and CMS jointly establish relevant certification criteria associated with the health information technology used to further administrative efficiency, reduce clinician burden, and improve the patient experience. To accomplish this, the Task Force suggests that federal payment programs provide targeted incentives that address the challenges of small practices to implement new standards, i.e., access to capital, lack of on-board technical expertise, and a clear need for aggressive outreach and education.

**MGMA comment:** We appreciate the emphasis the Task Force has placed on the need to assist smaller physician practices. These organizations typically have the least financial and technology resources and are often forced to leverage significant staff time to meet the myriad of health plan prior authorization requirements. We support the call for ONC and CMS to jointly establish relevant certification criteria and urged ONC to establish a certification process for practice management system (PMS) software, in addition to the current EHR software certification process. Having a PMS certification program in place would put market pressure on software vendors to develop and support automated prior authorization solutions and would increase practice purchasing confidence.

We also concur with the Task Force that the CMS Star or other ratings programs could be leveraged to improve the current prior authorization environment. The goal of these rating programs should be to reduce the administrative burden for physician practices associated with

meeting plan prior authorization requirements and improve the care that practices deliver to patients.

The following prior authorization measures could be incorporated into the CMS Star Ratings Program:

- Adherence to the CAQH CORE Prior Authorization Operating Rules. The Council for Affordable Quality Healthcare Committee on Operating Rules for Information Exchange (CAQH CORE) was named in the Affordable Care Act as the authoring entity for operating rules that enhance the business functionality of mandated electronic transactions. CAQH CORE recently finalized updated operating rules (Prior Authorization & Referrals (278) Data Content Rule vPA.1.0, Prior Authorization & Referrals (278) Infrastructure Rule vPA.2.0, and Connectivity Rule vC3.1.0) that establish, among other requirements, maximum timeframes at key stages in the prior authorization process for both batch and real-time transactions.
- Receipt of the CAQH CORE Certification Seal. CAQH CORE offers a certification process to test and ensure Operating Rule compliance for health plans. CAQH awards CORE Certification Seals to entities that create, transmit or use the healthcare administrative and financial transactions addressed by the CAQH CORE Operating Rules. CORE Certification means a health plan has demonstrated that its IT system is operating in conformance with applicable requirements of a specific phase(s) of the CAQH CORE Operating Rules. MA plans could be required to establish that they have been awarded the CORE Certification Seal for the full suite of prior authorization Operating Rules.
- Adherence with transparency requirements. MA plans, not less frequently than annually and at a time and in a manner specified by CMS, would be required to submit the following information and make available on a public section of its website:
  - A list of all items and services that are subject to a prior authorization requirement under the plan and
  - A template of the clinical information the plan requires in order to fully adjudicate the prior authorization request for all items and services that are subject to a prior authorization requirement.
- Adoption of a policy excluding prior authorization requirements for procedures
  undertaken during the perioperative period. Adherence to a prohibition against
  imposition of prior authorization requirements with respect to any surgical procedure or
  otherwise invasive procedure (as defined by CMS), and any item furnished as part of such
  surgical or invasive procedure, if such procedure (or item) is furnished during the
  peroperative period of a procedure for which—(A) prior authorization was received from
  such plan before such surgical or otherwise invasive procedure (or item furnished as part
  of such surgical or otherwise invasive procedure) was furnished or (B) prior authorization
  was not required by such plan.
- Establishment of a "gold card" program excluding clinicians from prior authorization requirements. The MA plan would establish a program to exempt a provider from the prior authorization process for services designated by CMS upon a provider's demonstration of compliance with the plan's coverage, coding and payment rules. The MA plan will exempt providers that achieve a prior authorization provisional affirmation threshold of at least 90 percent during a semiannual assessment.

- Adoption of a policy excluding clinicians who are participating in a risk-based contract with the MA plan from prior authorization requirements. The MA plan would establish a program to exempt a provider from any prior authorization requirements if they entered into a contract with the plan that required the clinician take on one or two-sided risk.
- Meeting a threshold for provider adoption of the X12 278 electronic transaction. The MA plan would be required to meet a threshold (established by CMS) of affiliated provider adoption of the X12 278 Request for Review and Response (prior authorization) electronic transaction.

**Adoption of the X12 275 electronic attachments standard**. The MA plan would implement this standard and offer providers the option of using the X12 275 transaction standard to transmit clinical documentation in support of a prior authorization.

We also note that while the Task Force has called for "targeted incentives" to assist practices, the recommendations lack specificity. For example, in addition to the federal government developing a new incentive program designed to offer financial and educational assistance to physician practices deploying prior authorization technology, an incentive could leverage the current CMS Quality Payment Program by adding points for prior authorization technology deployment to the Improvement Activity component of the Merit-based Incentive Payment System.

Recommendation 2: Establish a Government-wide Common Standards Advancement Process

The Task Force recommends that ONC, working in concert with CMS and other relevant Federal Agencies (including, but not limited to, Department of Defense and Tricare, Department of Veterans Affairs, and the Office of Personnel Management/Federal Employee Health Benefits Program) establish a single consistent process for standards advancement for relevant standards for health care interoperability, including transactions, code sets, terminologies/vocabularies, privacy and security used for conducting the business of health care, irrespective of whether that business is clinical or administrative. The existing authority granted to the Secretary under HIPAA (42 U.S. Code § 1320d) for evolution of standards should be sufficient to create an appropriate process that is responsive, reliably predictable, and imposes minimal burden relative to benefit received. The Task Force recommends that the standards advancement process incorporate multiple rounds of development testing and production pilot use prior to adoption as national standards.

**MGMA comment**: We agree that that additional steps are necessary to improve the process of identifying and adopting new and revised administrative standards and we urge the Task Force to offer specific steps to assist this process. These additional steps could include:

- Evaluating new or revised administrative standards;
- Facilitating testing and establishing pilots of potential new or revised administrative standards;
- Determining the return on investment (ROI) for potential new or revised administrative standards; and
- Collaborating with CMS and industry stakeholders on outreach and education.

We do not believe, however, that there is a necessity for a new entity to be created to perform those tasks. The National Committee on Vital and Health Statistics (NCVHS) is well positioned to evaluate current organizations for their ability to perform one or more of these tasks and encourage HHS to recognize these current entities. NCVHS itself could serve to include these entities in its oversight hearings and consider their findings in your deliberations for recommendations to the Secretary.

# **Recommendation 3**: Converge Health Care Standards

The Task Force recommends that ONC, working in concert with CMS, the National Library of Medicine (NLM), voluntary consensus standards organizations, and other relevant federal agencies (including but not limited to Department of Defense and Tricare, Department of Veterans Affairs, and the Office of Personnel Management/Federal Employee Health Benefits Program) harmonize standards to create a consistent set of standards for Code Sets, Content and Services that are evolved together to address multiple workflows, both clinical and administrative. The harmonized standards should use an underlying data model that is sufficiently comprehensive to serve both clinical and administrative needs.

The Task Force recognizes that different standards development organizations may have particular expertise, and the Task Force recommends that ONC, working with those standards development organizations, establish domains of expertise around common standards. For example, if it is determined that HL7 FHIR is a logical choice for the initial underlying content model, ONC would logically work with ASC X12 and NCPDP to establish authority for the FHIR domain for the relevant administrative standards, even though the underlying content model is defined by HL7. The intent is for a patient-centric model that would underline both the clinical workflow and administrative processes. From wherever data originated in the interoperable system, they should flow to wherever they are needed without having to be manually re-captured or re-entered if the data remain clinically applicable. The harmonized clinical and administrative standards should take into account the differences in data and workflow needs required by clinical and administrative processes. It is important to clarify that the Task Force's recommendation to harmonize standards does not imply that the complete clinical or administrative record should be sent with all administrative transactions or that legitimate users of the data should have unfettered access to the complete data set; the principle of minimum necessary must still apply.

**MGMA comment**: We concur with the Task Force recommendation calling on the ONC to work with standards development organizations and establish domains of expertise around common standards. We would urge, however, that the Task Force reiterate in its recommendation that the vast majority of physician practices, health plans, and vendor trading partners are using X12 transactions to conduct administrative business. Testing alternative and innovative approaches is critical, but we must not lose sight of the importance of improving the current X12 transactions environment. Although we recognize that the X12 278 prior authorization transaction is underused, that is a product, at least partially, of not having a complimentary electronic attachments standard. Once the X12 275 attachments standard is widely used, we anticipate use of the X12 278 will significantly increase.

### Recommendation 4: Provide a Clear Roadmap and Timeline for Harmonized Standards

The Task Force recommends that ONC, working in concert with the aforementioned organizations, establish a clear roadmap and timeline for harmonized standards, following the common standards advancement process, including adequate pilot and production usage, to raise the national floor.

**MGMA comment**: MGMA agrees there is a need for increased speed and predictability in the development and implementation of standards and operating rules. However, there are certain factors that influence the pace that regulations are promulgated that must be taken into account. Requiring the publication of regulations within one year of receipt and acceptance of a recommendation for a new or updated standard or operating rule may not always be appropriate as factors such as other regulations that would compete for physician practice resources may necessitate use of an alternative timeline best for the industry.

Understanding that this one-year publication mandate most likely would need to be a new statutory requirement, and as such is unlikely, forcing a regulation to be issued by the Department

prior to the appropriate level of review and modification could have unintended and negative consequences.

Rather than taking the approach of mandating government compliance with a set timeframe, MGMA recommends the Task Force support following process to achieve enhanced speed and improved predictability:

- Conduct a business need and ROI analysis. Prior to NCVHS making a formal
  recommendation to HHS to move forward with a new standard or operating rule, a
  comprehensive review of the business need for the standard or operating rule, the
  problems, concerns or limitations with the current standard (if there is one already being
  used by the industry), and evidence of a clear return on investment related to the new
  standard or operating rule should be untaken.
- Adopt individual transaction standards as opposed to a full version (i.e., X12 7030). There
  may be a business need and clear return on investment for an update to a specific
  standard (i.e., 5010 278) but less clear value for other transactions. NCVHS should be
  able to recommend adoption of a specific standard and not be forced to incur the lengthy
  process required to evaluate a full new version.
- Engage with physician practices. Any new or updated standard must work for practicing physicians in their efforts to deliver care to their patients. As such, NCVHS and the SDOs should augment its engagement with physician practices and ensure that smaller provider organizations are also consulted during the standards development process.
- Engage with the vendor community. Without the engagement and support of the EHR, practice management system, and billing system communities, the implementation of new standards will be protracted at best, impossible at worst. These vendors are linked directly with providers and if the vendors cannot or will not implement federal mandates providers cannot take advantage of the efficiencies associated with these new or revised standards. These vendors need to be consulted throughout the standards development process.

The issue of the ability of the SDOs to expeditiously update the standards is also a critical issue. The Task Force could recommend that NCVHS work directly with each of the SDOs to identify opportunities to streamline the standards development process. We need to look at the consequences of adopting updated standards every two years as there are significant costs to all organizations when implementing an updated version of standards, including system changes, testing, training, purchasing implementation guides, and resolving issues found in production. The costs of implementing updated standards and operating rules needs to be balanced against the anticipated benefits.

#### **Recommendation 5:** Harmonize Code and Value Sets

The Task Force recommends that ONC work with CMS, NLM, and relevant value set authorities to harmonize code and value sets to serve clinical and administrative needs. Where specialized code and value sets are needed, they must be mapped to more general code and value sets. As an example, in order to streamline prior authorization workflows, the code and value sets used to encode orderables, procedures, or referrals must be reusable across or cleanly mappable or cross-walked to the code and value sets used to determine administrative authorization for payment for the relevant orderable, procedure, or referral. The Task Force finds applicable to this harmonization the work of the National Committee on Vital and Health Statistics (NCVHS), specifically its February 13, 2019 recommendations on Terminology/Vocabulary adoption/implementation processes and on Guidelines for Curation and Dissemination (attached as Appendix XX)

#### MGMA comment:

We support the Task Force's identification of the need to harmonize code and value sets.

# **Recommendation 6:** Make Standards (Code Sets, Content, Services) Open to Implement Without Licensing Costs

End-user licensing of adopted standards, code sets and vocabularies is burdensome. In order to drive innovation and make standards-based capabilities available to the widest set of actors, the Task Force recommends that converged standards (and their included component code sets, etc.) named in certification programs be available to implementers without licensing costs for developers implementing the named standards. Ideally, such converged standards would be available via one of the business models that support full and open access to standards (e.g., NLM national licensing for code sets or standards development business models, such as those deployed for HL7 FHIR or Internet standards, that support member prioritization for the advancement of standards while making the resulting standards and implementation guidance available through broad usage licensing); alternatively, fair, reasonable and nondiscriminatory licensing may be imposed for production use or marketing claims of conformance.

**MGMA comment:** While we understand the sentiment behind recommending that code sets be made available without licensing fees, we contend that removing the licensing fees could have unintended consequences. For professional organizations, the fees are critical to ensuring the integrity of code sets through employing a thorough and rigorous development and maintenance process. For example, the Current Procedural Terminology (CPT) code set involves the direct input of practicing physicians, allied health professionals, and advisors from over 100 medical specialty societies. These groups develop concise and uniform codes used for research, processing claims, and developing guidelines for medical care. This work, however, requires a considerable financial investment, which is offset through licensing fees.

# **Recommendation 7**: Develop Patient-centered Workflows and Standards

The ICAD Task Force discussed the critical importance of patient access and the engagement of the patient into key administrative workflows. These workflows define access to and reimbursement for care, and delays in these workflows are a key source of care delays and suboptimal outcomes within the health care system. Accordingly, "Patient at the Center" must be a system-design philosophy and built in from the ground up. The patient and caregivers must be at the center of administrative workflows, and standards must be developed that engage the patient as a key actor. The Task Force believes such "administrative" information is part of the Designated Record Set (DRS) (as it is patient-specific information used for decision making). If there is uncertainty on the inclusion of administrative workflows in the DRS, the Task Force recommends ONC work with OCR to clarify the status of administrative workflows under the access provisions of HIPAA and ensure that patients have digital access to such data. The ICAD Task Force recommends that ONC work with other federal actors and standards development organizations to prioritize and develop administrative standards that are designed for patients' digital access and engagement. Even "workhorse" administrative standards like eligibility, claiming, and electronic EOB/remittance that are traditionally considered provider-to-payer should allow access through the same API frameworks already supporting API access. Converged clinical and administrative workflows, including prior authorization, should be designed to support API access and patient engagement as a matter of course. As an example, benefits information provided to the provider via eligibility transactions should also be available to the patient via APIs; the content and status of claiming/remittance should be available to the patient not only at the end of the process through the current EOB API, but throughout the process of claiming and adjudication. As another example, the patient should have the ability to bi-directionally share health data (including patient generated data) with providers and other third parties from their applications of choice without special effort.

**MGMA comment**: While we fully support the goal of a healthcare delivery system that is patient-centric, we believe that the prior authorization process presents a unique set of challenges that serve as barriers to achieving this Task Force recommendation.

There is a significant risk of harm to a patient, should they be placed in the center of the authorization process. Even for seasoned practice professionals, the complex proprietary prior authorization process employed by the different health plans is daunting, frustrating, and time consuming. Having the patient at the center of the prior authorization process could result in unintended consequences that would lead to delayed or denied care.

Even with well-informed, well educated, and highly motivated patients or their caregivers, we would anticipate significant delays in the authorization process as a result of not knowing the specific health plan reporting and/or clinical documentation requirements. Patients would be required to potentially work with multiple providers (i.e., physician, imaging center, lab) to gather the required clinical information (assuming they even knew what specific information the health plan required). Once compiled, this information would then need to be transmitted manually to the health plan (or its designated prior authorization vendor) for adjudication. Should the authorization be denied, the patient would then be required to lodge an appeal with supporting documentation, without having the requisite medical knowledge to support their case. This cumbersome process would be exacerbated greatly for those patients who are not as well educated or do not have access to the Internet. Marginal groups with few resources in particular would be more likely to suffer adverse health effects due to this process.

Should prior authorization be left in the hands of the patients themselves, it is not difficult to imagine scenarios where health plans would use patient-specific "guidelines" and "directives" as additional hurdles to authorizations. Patients, unaware of these guidelines and directives, may not even know that an authorization is required and will simply assume that their plan product does not cover a particular medication or service. Again, this could result in patients not getting the care they need and deserve.

While the Task Force envisions an environment where APIs permit easy access to health information, we still anticipate issues with prior authorization. APIs having the ability to curate health information from multiple sources and present a succinct and accurate health record for use by the patient during a prior authorization are years away from production, if ever. Even having an API that captures clinical data, the patient would still be required to know exactly what information the health plan required for an authorization and the patient would still have to interact with the plan to transmit the requisite information. Again, marginal groups with less access to technology would be significantly hindered during this process.

We do support having a more informed and engaged patient during the prior authorization process. Should they wish to be, patients should be given the option of participating in the authorization process (i.e., contacting their health plan ahead of a procedure to determine if a prior authorization is required). This type of patient-provider partnership can be advantageous to both and can actually speed up the process. In the real world of healthcare, however, patients are typically very willing to have their provider take on the primary role and burden of contacting their health plans and transmitting the clinical documentation required to support an authorization request.

### Recommendation 8: Create Standardized Member ID

The ICAD Task Force recommends that ONC work with CMS (for Medicare, Medicaid, Medicare Advantage and MADPs), OPM/FEBP and DOD/Tricare) to create and incorporate standards for member ID cards (following on INCITS 284-2011; reaffirmed as INCITS 284-2011 (R2016)). Alternatively, a virtual ID card could be permissible provided it complies with the INCITS ID card capability requirements and HIPAA privacy/security requirements. Standard IDs would reduce

burden by supporting patient access, clinical and administrative automation, and transparency between member/patient, provider, and plan. Member ID should be sufficient, along with HIPAA-appropriate levels of assurance, to reference patient specific plan and product requirements like drug formularies and prior authorization.

**MGMA comment**: We were pleased to see the Task Force identify the issue of member ID as one that could improve the prior authorization process. The member ID spans several issues, each of which could impact administrative processes. First, standardizing the member ID card and mandating a standard for machine-readability would serve to decrease administrative burden and cost and could be leveraged to automate both the insurance eligibility verification and the prior authorization process. As the recommendation alludes to, this card could be virtual and include a QR code that would provide machine-readability with properly equipped practice management system software.

The catalyst for this type of standardized member ID should have been the recent switch to the Medicare Beneficiary Identifier. In fact, MGMA and other organizations called on CMS to take advantage of this transition to issue the new Medicare cards with machine readability (either plastic or virtual cards). However, CMS refused to incorporate this functionality into the new Medicare card. Clearly the challenge is achieving this level of member ID standardization and automation without government support and without a government mandate. Even in the unlikely event that government health plans moved to standardized and machine-readable member ID cards, without the commercial plans also supporting this standard, widespread industry adoption by practice management system vendors and providers is unlikely.

# Recommendation 9: Name an Attachment Standard

The ICAD Task Force recommends that ONC work with CMS and other federal actors to establish a national approach to exchanging clinical data needed to support clinical information exchange, whether for care delivery or for administrative processes. Consistent with previous NCVHS recommendations and this report, an attachment standard must be evolved that reduces burden by harmonizing standards to ensure granularity of data to achieve automation.

**MGMA comment**: The current practice for medical groups is to fax, mail, or upload to proprietary websites the clinical data necessary to conduct prior authorizations. By leveraging EHR technology, the electronic attachment standard (X12 275) would automate the collection and transmission of clinical data in support of a prior authorization. Mandated by Congress in HIPAA (1996) and re-mandated in section 1104 of the Affordable Care Act in 2010, CMS has not yet issued a final regulation naming the standard. This standard, in addition to transmitting clinical documentation requirements for prior authorization, can significantly reduce administrative burden by supporting claim submissions, referrals, transitions of care, care coordination documentation requirements, and simplifying other patient data communication needs.

Although CAQH did not collect data regarding the industry use of associated costs of attachments for its 2018 report, it did collect this information for its 2017 report. With no government mandate for health plans to support the electronic attachment standard, as there is with the other HIPAA electronic transaction standards, industry adoption of the electronic attachment was at 6 percent.

CAQH did identify potential savings for health plans and providers adopting the electronic attachment standard. Health plan cost for a manual attachment is estimated by CAQH to be \$1.74. The cost to a health plan for an electronic attachment is \$.10 for a total health plan savings per attachment transaction of \$1.64. For providers, the cost for a manual attachment is estimated by CAQH to be \$1.68, \$1.17 for an electronic attachment, for a savings of \$.051 per attachment. Combined, industry savings per attachment transaction would be \$2.15.

(Note that CAQH captured data on attachment usage and cost only related to use of the attachment in support of a claim submission, not a prior authorization request. The savings associated with use of the transaction for authorizations would likely be greater as a clinical data submission in support of a claim typically requires less data than what is required to support a prior authorization request.)

While we appreciate the Task Force identifying the need to establish an attachment standard, we believe this message is diluted somewhat by not fully developing the recommendation for CMS and ONC to develop X12-based workflow prior authorization solution. We agree that FHIR-based administrative transactions (including prior authorization) show great promise and testing of these innovative approaches must be encouraged. However, the current transaction environment (workflows, technology, staff training, clearinghouse relationships) for almost all providers, health plans, and the vendors that support them, is X12 based. We recommend to the Task Force that the final report recognize the need to support, improve, and augment the X12 prior authorization and attachment transactions.

# **Recommendation 10**: Establish Regular Review of Prior Authorization Rules

The ICAD Task Force recommends that ONC work with CMS and other federal actors to establish consistent processes and guidelines for prior authorization rulesets to apply to CMS, MA, FEHP, and other similar federally controlled or contracted plans. Such processes should simplify rules, and remove rules that have high burden (e.g., those that are frequently approved, frequently overturned on appeal, or otherwise have low utility) and reviews should take place no less frequently than annually. The ICAD Task Force recommends that ONC work with CMS and other relevant Federal actors to establish transparency in the Prior Authorization process via published metrics on authorization and denial rates, rates of appeal, and metrics on appeals.

**MGMA comment**: We concur with the Task Force recommendation calling on federally controlled or contracted health plans to be transparent and be required to publish metrics on services that are frequently approved, authorization and denial rates, rates of appeal, and appeals. We note that this same provision is included in bipartisan Improving Seniors' Timely Access to Care Act of 2019 (HR 3107), now with 262 co-sponsors. We recommend the Task Force to expand this requirement to all covered entity health plans.

We also urge the Task Force to expand this recommendation and require that health plans publicly disclose, in a searchable electronic format, patient-specific utilization management requirements, including prior authorization, step therapy, and formulary restrictions with patient cost-sharing information, applied to individual drugs and medical services. Such information should be accurate and current and include an effective date in order to be relied upon by providers and patients, including prospective patients engaged in the enrollment process. Additionally, health plans should clearly communicate to prescribing/ordering providers what supporting documentation is needed to complete every prior authorization and step therapy override request.

Further, this recommendation highlights that prior authorization rules that should be removed when they result in high burden and have otherwise low utility. While we strongly agree with this sentiment, we urge the Task Force to expand this recommendation. There are numerous opportunities to reduce the volume of prior authorizations without significantly impacting a health plans ability to manage utilization. These opportunities include:

- Removing prior authorizations for routine services
- Removing prior authorizations for medications for chronic illnesses (where patients are on a particular medication for life)
- Removing prior authorizations for generic medications
- Removing prior authorizations for perioperative services

- Bundling prior authorizations (i.e., knee replacement PA would include pre/post visits, medications, PT, DME)
- Removing prior authorizations for providers in risk-contracts
- Instituting "gold card" programs for high performing providers, exempting them from prior authorization requirements

#### Recommendation 11: Establish Standards for Prior Authorization Workflows

The ICAD Task Force recommends that ONC work with CMS, other Federal actors, and standards development organizations to develop programmatic (API) specifications to create an authorization (electronic Prior Authorization or related determinations such as Medical Necessity) such that the authorization and related documentation can be triggered in workflow in the relevant workflow system where the triggering event for the authorization is created. As an example, when an authorization is required for payment for a procedure or referral for evaluation or treatment, the prior authorization workflow should be enabled in the relevant ordering or referral clinical workflow. The Task Force recommends that the chosen standard or standards be sufficient to:

- Determine which orderables, procedures, referral or other activities are subject to prior authorization, medical necessity or other similar pre-approval checks
- Determine the requirements and rules for approval of an orderable, procedure, referral, etc. sufficient to collect the required documentation or justification
- Automate the pre-approval workflow using the provider's chosen technology platform without relying on portals or payer-specific workflows
- Determine the definitive status of a pre-approval request programmatically in the provider's chosen workflow
- Ensure that transparency occurs in near real-time, based on a specific patient at a specific time in a specific location. The Task Force recommends that ONC work with CMS and other Federal actors overseeing benefits plans (e.g., Tricare, FEHP) to establish policy mechanisms to provide or incent increased benefit transparency and automated electronic prior authorization. The Task Force further recommends that these regulations and requirements for trading partners include service level objectives on latency and availability sufficient for prior authorization to be incorporated in interactive workflows. The Task Force further recommends that standards and implementation guidance specify requirements on denials such that denials are accompanied with clear, complete and computable reason for denial such that actors can correct, if relevant and applicable, causes for denial. The standards and implementation guidance should require any denial to address all deficiencies in the request, i.e., must evaluate the entire request and not simply issue a denial citing only the first in a potentially longer sequence of identifiable deficiencies. Examples of emerging areas that should be looked at: o CDS Hooks supporting a variety of hook actions is needed for real time clinical decision support across multiple use cases o Full FHIR profiles o Bulk Data on FHIR for multiple use cases o Bidirectional data flow (to and from EHRs; read-write capabilities) o Standardized (open APIbased) electronic health information (EHI) Export functionality -for persistent, real-time EHI access for multiple provider-facing use cases (i.e., population health and outcomes management, analytics, research) o Ongoing refinement and updating of USCDI standardized data classes and data elements)

**MGMA comment**: We concur with the Task Force recommendation to develop programmatic (API) specifications to create an authorization (ePA or related determinations such as Medical Necessity) such that the authorization and related documentation can be triggered in workflow in the relevant workflow system where the triggering event for the authorization is created. However, we urge the Task Force to include stronger language that calls on CMS to mandate, with appropriate implementation timeframes, these actions on covered entity health plans. While

voluntary adoption of FHIR-based standards is important at the outset to better identify the return on investment for providers, health plans, and vendors, ultimately, these standards need to be mandated if the industry is to fully realize their benefits. Allowing health plans to pick and choose what standards they support will only lead to increased fragmentation and one-off proprietary solutions that only serve to increase administrative costs and burdens on providers.

We also support the call for near "real-time" health plan transparency. Again, however, we urge the Task Force to use stronger language and call on CMS to, for example, require health plans to support, when fully developed, the Document Requirement Lookup Service (DRLS) approach currently being piloted by the agency. Leveraging FHIR standards, this near real-time program informs the provider if a prior authorization is required for a particular service and sends the clinical documentation template to the provider's EHR for purposes of supporting the required authorization or to support a post-payment audit.

Health plans should also be required to provide detailed explanations for prior authorization or step therapy override denials, including an indication of any missing information. All denials from the health plan should include the clinical rationale for the adverse determination (e.g., national medical specialty society guidelines, peer-reviewed clinical literature, etc.), provide the plan's covered alternative treatment, and detail the provider's appeal rights.

We assert that real-time electronic prior authorization transactions will reduce cost for health plans and providers by eliminating manual (fax, phone, proprietary payer web portal) provider communications with the plan. These real-time decisions would be for routine medical services and medications that are approved at an extremely high rate. These are medical services and medications that would not typically require the submission of supporting documentation from the provider to the plan.

These real-time decisions for routine medical services and medications could mirror the current approach that providers and health plans leverage for verifying insurance eligibility and benefits. Under the 2011 CMS interim final rule, health plans are required to support a real-time eligibility and benefits verification transaction with the rule stipulating on page 40465 that "The maximum response time when processing in real time mode must be 20 seconds or less."

The ONC November 2018 report "<u>Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs</u>" outlines some of the many challenges associated with the current prior authorization processes and offers recommendations on how to improve those processes. On page 14 of the report, ONC recommends the following strategy: "*Leverage health IT to standardize data and processes around ordering services and related prior authorization processes*." Later in the report (page 19) ONC signals its clear support for real-time electronic prior authorization transactions when it makes the following recommendation: "*Support automation of ordering and prior authorization processes for medical services and equipment through adoption of standardized templates, data elements, and real-time standards-based electronic transactions between providers, suppliers and payers."* 

#### Recommendation 12: Create Extension and Renewal Mechanism for Authorizations

The ICAD Task Force recommends that ONC work with other federal actors and standards development organizations to develop programmatic (API) specifications to renew or extend an authorization where prior authorization applies to services that have long durations. The Task Force recommends that ONC work with CMS and other Federal actors overseeing benefits plans (e.g., Tricare, FEHP) to ensure that authorizations can be renewed through these means without requiring a new authorization and that such renewals and the status of existing authorization be enabled via standards-based APIs.

**MGMA comment**: We concur with the Task Force recommendation to develop programmatic (API) specifications to renew or extend an authorization where prior authorization applies to services that have long durations. Patients forced to interrupt ongoing treatment due to health plan utilization management coverage restrictions could experience a negative impact on their care and health. In the event that, at the time of plan enrollment, a patient's condition is stabilized on a particular treatment that is subject to prior authorization or step therapy protocols, a health plan should permit ongoing care to continue while any prior authorization approvals or step-therapy overrides are obtained.

Health plans should offer an appeals system for their utilization management programs that allows a prescribing/ordering provider direct access, such as a toll-free number, to a provider of the same training and specialty/subspecialty for discussion of medical necessity issues. Plans should also allow for flexibility, including the timely overriding of step therapy requirements and appeal of prior authorization denials.

Any utilization management program applied by a health plan to a service, device or medication should be based on accurate and up-to-date clinical criteria and never cost alone. The referenced clinical information should be readily available to the prescribing/ordering provider and the public.

Many patients carefully review formularies and coverage restrictions prior to purchasing a health plan product in order to ensure they select coverage that best meets their medical and financial needs. Unanticipated changes to a formulary or coverage restriction throughout the plan year can negatively impact patients' access to needed medical care and unfairly reduce the value patients receive for their paid premiums. Further, many conditions require ongoing treatment plans that benefit from strict adherence. Recurring prior authorizations requirements can lead to gaps in care delivery and threaten a patient's health.

Many health plans employ step therapy protocols, under which patients are required to first try and fail certain therapies before qualifying for coverage of other treatments. These programs can be particularly problematic for patients—such as those purchasing coverage on the individual marketplace—who change health insurance on an annual basis. Patients who change health plans are often required to disrupt their current treatment to retry previously failed therapeutic regimens to meet step therapy requirements for the new plan. Forcing patients to abandon effective treatment and repeat therapy that has already been proven ineffective under other plans' step therapy protocols delays care and may result in negative health outcomes.

The Task Force should recommend that no health plan be permitted to require patients to repeat step therapy protocols or retry therapies failed under other benefit plans before qualifying for coverage of a current effective therapy.

# Recommendation 13: Include the Patient in Prior Authorization

The ICAD Task Force recommends that ONC work with CMS and other Federal actors administering health benefits (e.g., FEHP, Tricare, VHA) to ensure that prior authorization systems be designed with patient engagement as a critical design goal, such that the patient is included throughout the process. In particular, the patient (or designee) should receive notification and status of key activities and have the ability to view content associated with the prior authorization (for informed decision making and correction) and provide patient-generated information into the prior authorization process (e.g., ability to point out errors and to respond to such questions, if any, which only the patient herself/himself or caregiver can answer).

**MGMA comment**: As we stated in our comment on Recommendation # 7, there is a significant risk of harm to a patient, should they be placed in the center of the authorization process. Even for seasoned practice professionals, the complex proprietary prior authorization process used by the different health plans is daunting, frustrating, and time consuming. Having the patient at the center

of the prior authorization process could result in unintended consequences that would lead to delayed or denied care.

In today's environment, physician practices work closely with the patients to design a treatment plan that works with what insurance product they present with. Further, as an integral part of the care delivery process, practices interact directly with their patients to get the information required by their health plan to authorize a medication or service. Patients are consulted when issues arise with the authorization process and clinicians and patients work together to determine treatment options should the patient's health plan deny coverage.

Recommendation 14: Establish Patient Authentication and Authorization to Support Consent

Create standards that will enable patients/caregivers to authorize sharing of their data with the tool of their choice to interface with their corresponding provider and payer systems. HHS should establish a standard for 3rd party patient authentication that allows patients to access and bidirectionally share their data across the landscape (i.e., from all their providers, payors, and actors such as clearinghouses, HIEs, and Public Health), utilizing a consistent authentication and authorization token allowing them easier integration with their health data application.

**MGMA comment**: We are not convinced that a recommendation to create standards that will enable patients/caregivers to authorize sharing of their data with the tool of their choice to interface with their corresponding provider and payer systems is necessary. Currently, HIPAA permits the provider to share a patient's health data with a health plan for purposes that include prior authorization. Patient consent is not required for this action. Further, the ONC final Cures Act regulation clearly requires the provider to share health information with a 3<sup>rd</sup> party app at the direction of the patient. Once the patient has this data, it is up to them to decide how to use or who to transmit it to. As we have stated previously, however, having patients bear the burden of conducting a prior authorization, even if they have their complete medical record on their mobile device, will slow the care delivery process, result in adverse health events, and unfairly discriminate against those less educated and those with reduced access to technology.

#### Recommendation 15: Establish Test Data Capability to Support Interoperability

HHS should lead development of a national approach to have test data beds to drive innovation and ensure real-world functionality and interoperability. To accomplish this, the following actions are needed: • Review the current administrative transactions and associated value/code sets to ensure USCDI supports data concepts and elements needed downstream to support clinical and administrative function; • Establish (illustrative) information models, in stages, to align clinical and administrative data for secondary use in stages based on the highest societal priorities.

• Establish a Minimum Data Set for transactions at the intersection of clinical and administrative data that adheres to "minimum necessary" requirements. • Advance an appropriately constrained implementation guide as a standard.

**MGMA comment**: Developing a national approach to have test data beds drive innovation and ensure real-world functionality and interoperability would be an important step forward in the effort to decrease the administrative burden associated with prior authorization. While there is currently a process to request from CMS an exemption from the HIPAA requirements, few entities take advantage of this opportunity to explore new and innovative approaches to administrative transactions. One of the challenges with testing new innovations is a lack of federal funding for such initiatives. We would encourage the Task Force to call on CMS to fund these tests and pilots and help establish the ROI for the participating stakeholders.

## Conclusion

In conclusion, MGMA again would like to thank the Task Force for taking on the mission of identifying opportunities to integrate clinical and administrative data and developing recommendations to ease the prior authorization burden for providers and their patients. Considerable work must still be accomplished, however, to overcome the numerous technical and business barriers to solve prior authorization challenges.

Through implementation of appropriate policies, processes, and incentives, we are hopeful that the industry can address the volume, transparency, and automation issues that waste limited healthcare resources and result in adverse health outcomes for many patients. We look forward to working with the Task Force, with CMS, ONC and other federal agencies to facilitate the industry's transition to a more effective and efficient prior authorization process for medications and services. Should you have any questions regarding these comments, please contact Robert Tennant, Director, Health Information Technology Policy, at 202.293.3450 or rtennant@mgma.org.

Sincerely,

/s/

Anders Gilberg, MGA Senior Vice President, Government Affairs

CC:

Donald Rucker, MD National Coordinator, Office of the National Coordinator for Health Information Technology

Mary Greene, MD Director, Office of Burden Reduction and Health Informatics Centers for Medicare & Medicaid Services