AMA
AMERICAN MEDICAL ASSOCIATION

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May 2, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Electronic Attachment Standard

Dear Administrator Verma:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to urge the Centers for Medicare & Medicaid Services (CMS) to promptly release a rule creating a standard for electronic clinical attachments. The current process of sending supporting clinical documentation by fax or mail is antiquated, costly, and administratively burdensome to both physicians and health plans, and can lead to significant delays in patient treatment. Industry-wide adoption of electronic clinical attachments has the potential to significantly improve process efficiencies, reduce time to treatment, and advance the Administration's and AMA's shared goal of improved interoperability. The AMA applauds CMS' Patients Over Paperwork initiative and believes that advancing the adoption of electronic clinical attachments would contribute to those efforts.

A July 2016 National Committee on Vital and Health Statistics (NCVHS) letter, "Recommendations for the Electronic Health Care Attachment Standard," in which NCVHS outlines the need for adoption of an electronic attachment standard under the Health Insurance Portability and Affordability Act (HIPAA) administrative simplification provisions, states that current attachment processes delay claim adjudication by an average of 25-30 days. Congress enacted the HIPAA administrative simplification provisions to enable physicians and other providers "to submit the same transaction to any health plan in the United States" electronically.[1] In support of this principle, the U.S. Department of Health & Human Services (HHS) has mandated current HIPAA standards to streamline the process for electronically completing health care transactions. These standardized transactions promote efficiency in the industry by eliminating the need for physicians to reformat transactions to meet specific requirements of

[1] HHS Frequently Asked Questions about Electronic Transaction Standards Adopted Under HIPAA. Available at https://aspe.hhs.gov/report/frequently-asked-questions-about-electronic-transaction-standards-adopted-under-hipaa.

each health plan to which they submit claims and other revenue cycle data exchanges, which can be numerous. In contrast, while each health plan may plainly disclose their format specifications for attachments, physicians must track the requirements of each plan across hundreds, if not thousands, of claims and other transactions requiring clinical documentation, resulting in significant administrative strain on their practice. **Stakeholders should not be forced to support multiple ways of electronically transmitting the same information. We therefore encourage CMS to mandate a single format for clinical information and a single enveloping method in the attachment standard so that physicians are not required to accommodate the unique specifications of each particular health plan with which they do business.**[2]

The AMA sees a particularly urgent need for an electronic attachment standard due to its integral connection to prior authorization automation and its impact on patient care, as most prior authorizations for medical services require additional supporting clinical documentation. As detailed in the enclosed results from a 2017 survey conducted by the AMA, prior authorization requirements are a significant pain point for physicians, their staff, and their patients. In particular, 92 percent of 1000 surveyed physicians stated that prior authorization had a negative impact on patient clinical outcomes; 61 percent of the physicians surveyed characterized this negative impact as "significant." Additionally, 92 percent of surveyed physicians reported that prior authorization requirements delay access to necessary patient care and 78 percent reported that the need for prior authorization can lead to a patient abandoning their recommended course of treatment. The survey also found that 86 percent of surveyed physicians report increased burden associated with prior authorization over the past five years; 51 percent stated that the increase is "significant."

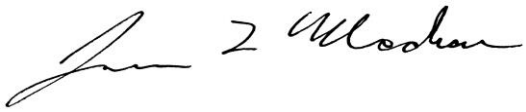
Stakeholders across the health care industry recognize the need to reverse the alarming trajectory of prior authorization burdens. In a Consensus Statement on Improving the Prior Authorization Process, released by the AMA, the insurance industry's trade group, the America's Health Insurance Plans, the Blue Cross/Blue Shield Association, and other stakeholder organizations announcing their commitment to improving the prior authorization process (enclosed), the parties agreed to "advocate for adoption of national standards for the electronic exchange of clinical documents (i.e., electronic attachment standards) to reduce administrative burdens associated with prior authorization." An electronic attachment standard is also a necessary and critical component of an end-to-end automated prior authorization process.

Even beyond prior authorization process improvements, all industry stakeholders and patients would benefit from a standard electronic method to exchange clinical data. The current process of sending supporting documentation by fax or mail is costly and burdensome to both the sender and recipient. Physician practices waste valuable dollars on postage and manual paper processing, while health plans bear the costs and inefficiencies of mailroom handling. The creation of an electronic attachment standard is extremely important in addressing these industry challenges and reducing administrative waste.

[2] For additional details about the AMA's recommendations related to attachment formats, please see our November 2016 letter to former HHS Secretary Sylvia Burwell (enclosed).

To promote efficiency and meet the goals of the legislation, the industry needs a single, uniform, defined way of formatting and enveloping clinical information to be exchanged between physicians and other practices, providers, or health plans. We urge CMS to release a Notice of Proposed Rulemaking (NPRM) adhering to these concepts to achieve administrative simplification throughout the health care industry. Should you wish to discuss any of these issues, please contact Laura Hoffman, Assistant Director of Federal Affairs, at laura.hoffman@ama-assn.org or 202-789-7414.

Sincerely,



James L. Madara, MD

Enclosures: 2017 AMA Prior Authorization Physician Survey
Consensus Statement on Improving the Prior Authorization Process
November 2016 letter to Former HHS Secretary Burwell

Consensus Statement on Improving the Prior Authorization Process

Our organizations represent health care providers (physicians, pharmacists, medical groups, and hospitals) and health plans. We have partnered to identify opportunities to improve the prior authorization process, with the goals of promoting safe, timely, and affordable access to evidence-based care for patients; enhancing efficiency; and reducing administrative burdens. The prior authorization process can be burdensome for all involved—health care providers, health plans, and patients. Yet, there is wide variation in medical practice and adherence to evidence-based treatment. Communication and collaboration can improve stakeholder understanding of the functions and challenges associated with prior authorization and lead to opportunities to improve the process, promote quality and affordable health care, and reduce unnecessary burdens.

The following five areas offer opportunities for improvement in prior authorization programs and processes that, once implemented, can achieve meaningful reform.

1. **Selective Application of Prior Authorization.** Differentiating the application of prior authorization based on provider performance on quality measures and adherence to evidence-based medicine or other contractual agreements (i.e., risk-sharing arrangements) can be helpful in targeting prior authorization requirements where they are needed most and reducing the administrative burden on health care providers. Criteria for selective application of prior authorization requirements may include, for example, ordering/prescribing patterns that align with evidence-based guidelines and historically high prior authorization approval rates.

   We agree to:

   - ***Encourage the use of programs that selectively implement prior authorization requirements based on stratification of health care providers' performance and adherence to evidence-based medicine***
   - ***Encourage (1) the development of criteria to select and maintain health care providers in these selective prior authorization programs with the input of contracted health care providers and/or provider organizations; and (2) making these criteria transparent and easily accessible to contracted providers***

- ***Encourage appropriate adjustments to prior authorization requirements when health care providers participate in risk-based payment contracts***

2. **Prior Authorization Program Review and Volume Adjustment.** Regular review of the list of medical services and prescription drugs that are subject to prior authorization requirements can help identify therapies that no longer warrant prior authorization due to, for example, low variation in utilization or low prior authorization denial rates. Regular review can also help identify services, particularly new and emerging therapies, where prior authorization may be warranted due to a lack of evidence on effectiveness or safety concerns.

   We agree to:

   - ***Encourage review of medical services and prescription drugs requiring prior authorization on at least an annual basis, with the input of contracted health care providers and/or provider organizations***
   - ***Encourage revision of prior authorization requirements, including the list of services subject to prior authorization, based on data analytics and up-to-date clinical criteria***
   - ***Encourage the sharing of changes to the lists of medical services and prescription drugs requiring prior authorization via (1) provider-accessible websites; and (2) at least annual communications to contracted health care providers***

3. **Transparency and Communication Regarding Prior Authorization.** Effective, two-way communication channels between health plans, health care providers, and patients are necessary to ensure timely resolution of prior authorization requests to minimize care delays and clearly articulate prior authorization requirements, criteria, rationale, and program changes.

   We agree to:

   - ***Improve communication channels between health plans, health care providers, and patients***
   - ***Encourage transparency and easy accessibility of prior authorization requirements, criteria, rationale, and program changes to contracted health care providers and patients/enrollees***
   - ***Encourage improvement in communication channels to support (1) timely submission by health care providers of the complete information necessary to make a prior authorization determination as early in the process as possible; and (2) timely notification of prior authorization determinations by health plans to impacted health care providers (both ordering/rendering physicians and dispensing pharmacists) and patients/enrollees***

4. **Continuity of Patient Care.** Continuity of patient care is vitally important for patients undergoing an active course of treatment when there is a formulary or treatment coverage

change and/or a change of health plan. Additionally, access to prescription medications for patients on chronic, established therapy can be affected by prior authorization requirements. Although multiple standards addressing timeliness, continuity of care, and appeals are currently in place, including state and federal law and private accreditation standards, additional efforts to minimize the burdens and patient care disruptions associated with prior authorization should be considered.

We agree to:

- ***Encourage sufficient protections for continuity of care during a transition period for patients undergoing an active course of treatment when there is a formulary or treatment coverage change or change of health plan that may disrupt their current course of treatment***
- ***Support continuity of care for medical services and prescription medications for patients on appropriate, chronic, stable therapy through minimizing repetitive prior authorization requirements***
- ***Improve communication between health care providers, health plans, and patients to facilitate continuity of care and minimize disruptions in needed treatment***

5. **Automation to Improve Transparency and Efficiency.** Moving toward industry-wide adoption of electronic prior authorization transactions based on existing national standards has the potential to streamline and improve the process for all stakeholders. Additionally, making prior authorization requirements and other formulary information electronically accessible to health care providers at the point-of-care in electronic health records (EHRs) and pharmacy systems will improve process efficiencies, reduce time to treatment, and potentially result in fewer prior authorization requests because health care providers will have the coverage information they need when making treatment decisions. Technology adoption by all involved stakeholders, including health care providers, health plans, and their trading partners/vendors, is key to achieving widespread industry utilization of standard electronic prior authorization processes.

We agree to:

- ***Encourage health care providers, health systems, health plans, and pharmacy benefit managers to accelerate use of existing national standard transactions for electronic prior authorization (i.e., National Council for Prescription Drug Programs [NCPDP] ePA transactions and X12 278)***
- ***Advocate for adoption of national standards for the electronic exchange of clinical documents (i.e., electronic attachment standards) to reduce administrative burdens associated with prior authorization***
- ***Advocate that health care provider and health plan trading partners, such as intermediaries, clearinghouses, and EHR and practice management system vendors, develop and deploy software and processes that facilitate prior authorization automation using standard electronic transactions***
- ***Encourage the communication of up-to-date prior authorization and step therapy requirements, coverage criteria and restrictions, drug tiers, relative***

costs, and covered alternatives (1) to EHR, pharmacy system, and other vendors to promote the accessibility of this information to health care providers at the point-of-care via integration into ordering and dispensing technology interfaces; and (2) via websites easily accessible to contracted health care providers

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November 22, 2016

The Honorable Sylvia Burwell
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

RE: Electronic Attachment Standard

Dear Secretary Burwell:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am pleased to submit the following comments in response to the recent National Committee on Vital and Health Statistics (NCVHS) letter "Recommendations for the Electronic Health Care Attachment Standard," in which the NCVHS outlines the need for adoption of an electronic attachment standard under the Health Insurance Portability and Affordability Act (HIPAA) administrative simplification provisions. We applaud the NCVHS for soliciting industry feedback and for providing thoughtful recommendations on this challenging and important topic.

As detailed in the NCVHS letter, current attachment processes delay claim adjudication by an average of 25–30 days. Accordingly, physicians are eager for an electronic attachment standard, as it would foster more timely payment for rendered services. However, the advantages of an electronic attachment standard are not limited to physicians. All industry stakeholders and patients would benefit from a standard electronic method to exchange clinical data. The current process of sending supporting documentation by fax or mail is costly and burdensome to both the sender and recipient. Physician practices waste valuable dollars on postage and manual paper processing, while health plans bear the costs and inefficiencies of mailroom handling. The creation of an electronic attachment standard is extremely important in addressing these industry challenges and reducing administrative waste, and we commend the NCVHS for recommending timely action on this matter. The AMA sees a particularly urgent need for an electronic attachment standard due to its connection to prior authorization automation. The ability to electronically submit supporting clinical documentation using a standard format across health plans is a necessary and indeed critical component of an end-to-end automated prior authorization process.

In addition, we agree with the NCVHS recommendation that the attachment standard be released as a Notice of Proposed Rule Making (NPRM) rather than an Interim Final Rule, as significant stakeholder input and feedback will be essential to ensure that the mandated standard meets the needs of users and is widely adopted. As noted by the NCVHS, considerable time has elapsed since the previous NPRM on

attachments, and the industry should be allowed another opportunity to comment based on current technology and workflows.

As expressed in the NCVHS letter, the adoption of one standard definition of "attachment" under HIPAA is an essential step to achieving administrative simplification. To create a practical and impactful attachment standard for the industry, however, the U.S. Department of Health and Human Services (HHS) needs to provide more specificity regarding the scope of the attachment standard than what is offered in the NCVHS recommendations. **We encourage HHS to mirror its 2005 NPRM in delineating the application of the attachment standard. The 2005 NRPM recommended that the attachment standard be applicable to any processes used directly in the claims payment process**, such as when clinical information is needed to make a determination of benefits or to establish medical necessity. Other clinical information requests were ruled out of scope for the attachment standard: "Although additional clinical or administrative information may be required following adjudication of claims . . . we do not consider these post-adjudication requests for claims-related data to be part of the claims payment process. Therefore, post-adjudication processes are not covered by this proposal."[1] We believe that this definition supports a clear application of the attachment standard and reflects a scope of work that can be realistically implemented by physicians and other stakeholders. Broad physician adoption will be critical in achieving the administrative simplification goals of the new attachment standard.

Our primary concern with the NCVHS recommendations is the allowance of multiple formats for both the clinical information and the transport mechanism to be used for electronic attachments. Although presented as a way of promoting flexibility in the standard, **the creation of multiple formats presents the potential for significant physician burdens and thus limits the ability to achieve the administrative simplification goals of the HIPAA legislation.**

Attachments and Administrative Simplification

Congress enacted the HIPAA administrative simplification provisions to enable physicians and other providers "to submit the same transaction to any health plan in the United States" electronically.[2] In support of this principle, HHS has mandated current HIPAA standards to streamline the process for electronically completing health care transactions. These standardized transactions promote efficiency in the industry by eliminating the need for physicians to reformat transactions to meet idiosyncratic health plan requirements.

In formulating its recommendations regarding an attachment standard, the NCVHS considered *consistency* (the ability to be implemented in the same manner across all health care entities) and *ambiguity* (differences in interpretation and in implementation). The concept of *flexibility* was also evaluated, and was defined as the ability to be adaptable and "allow for interim updates" (as opposed to permitting various methods of transmitting the same data). We strongly agree with this approach, as a standard that enhances consistency and reduces ambiguity, will better meet the overall goal of administrative simplification. Following this logic, the NCVHS advocates against the creation of multiple ways to exchange the same information through Recommendation 16, which asks HHS to

[1] 70 Fed. Reg. 55989 (Sept. 23, 2005). Available at https://www.federalregister.gov/documents/2005/09/23/05-18927/hipaa-administrative-simplification-standards-for-electronic-health-care-claims-attachments.
[2] HHS Frequently Asked Questions about Electronic Transaction Standards Adopted Under HIPAA. Available at https://aspe.hhs.gov/report/frequently-asked-questions-about-electronic-transaction-standards-adopted-under-hipaa.

"ensure that providers, payers and other industry stakeholders are not obligated to establish and maintain different standards-based infrastructures for different programs that require the exchange of similar data." **We agree that stakeholders should not be forced to support multiple ways of electronically transmitting the same information. We therefore encourage HHS to mandate a single format for clinical information and a single enveloping method in the attachment standard so that physicians are not required to accommodate the unique specifications of each particular health plan with which they do business.**

Attachment Formatting

In order to standardize the exchange of clinical information for administrative purposes, an attachment solution must establish formats for both the transport of the clinical document (often called the "envelope") and the clinical information itself. The Accredited Standards Committee X12 (ASC X12) has established and recommends usage of the 275 transaction as the standard administrative "envelope" format for electronic attachments. Additionally, Health Level Seven (HL7), the standards designation organization for electronic clinical data, has created the Consolidated Clinical Document Architecture Release 2.1 (C-CDA R2.1). Physicians routinely use the C-CDA R2.1 today to format patient care information to send to other provider clinical systems. Recently, HL7 also created the Clinical Documents for Payers – Set 1 (CDP1), which represents another format for clinical documentation.

Clinical Document Formatting:

Although the NCVHS recommends the C-CDA R2.1 as the clinical formatting standard, it also recommends that CDP1 be adopted as an additional, acceptable standard. We believe that allowing multiple ways of formatting clinical information under the adopted attachment standard could obligate physicians to use different processes and workflows for creating and exchanging the same clinical data. With physician systems and workflows already utilizing C-CDA R2.1, supporting the additional CDP1 standard for health plans requiring this format would create additional burdensome steps in the practice workflow. **For these reasons, we recommend that HHS mandate the C-CDA R2.1 as the single standard for formatting clinical information for electronic attachments.**

Document Transport (Enveloping):

The NCVHS recommends that the ASC X12 275 be mandated as the standard enveloping mechanism to transport clinical information from providers to health plans. We fully support this recommendation; however, we are concerned that the NCVHS also suggests that HHS "allow for alternative recognized standard envelope and transport options to transmit attachments to accommodate existing and future transport technologies." This language creates the potential for significant administrative burden for physicians, who interact with multiple health plans and would need to support numerous enveloping options and track each plan's required format. **As a result, we recommend that HHS establish the ASC X12 275 as the only enveloping standard for electronic attachments.**

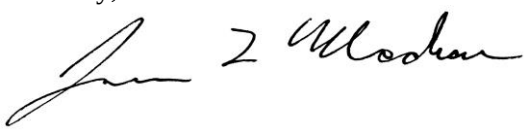
Conclusion

We appreciate the NCVHS's investment of time and resources in formulating its recommendations related to an electronic attachment standard, and we join the NCHVS in urging HHS to promptly address this significant industry need. While we agree with many of the NCVHS recommendations, we firmly

believe that an electronic attachment standard that allows multiple ways of formatting and transporting clinical information fails to accomplish the legislative objectives of HIPAA and is effectively not a standard. To promote efficiency and meet the goals of the legislation, the industry needs a single, uniform, defined way of formatting and enveloping clinical information to be exchanged between physicians and other practices/providers or health plans. We urge HHS to release an NPRM that adheres to these concepts in order to achieve administrative simplification throughout the health care industry.

Thank you for the opportunity to comment on the electronic attachment standard. Should you have any questions or wish to discuss any of these issues, please contact Laura Hoffman, Assistant Director of Federal Affairs, at laura.hoffman@ama-assn.org or 202-789-7414.

Sincerely,



James L. Madara, MD

cc: Shana Olshan

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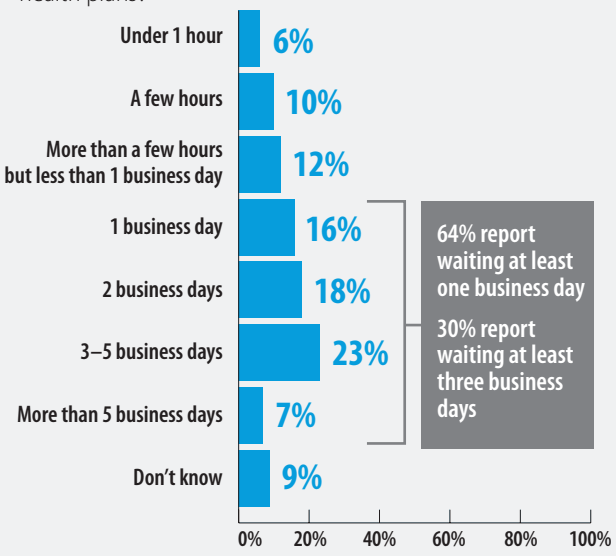
2017 AMA Prior Authorization Physician Survey

PATIENT IMPACT

Average wait time for PA responses

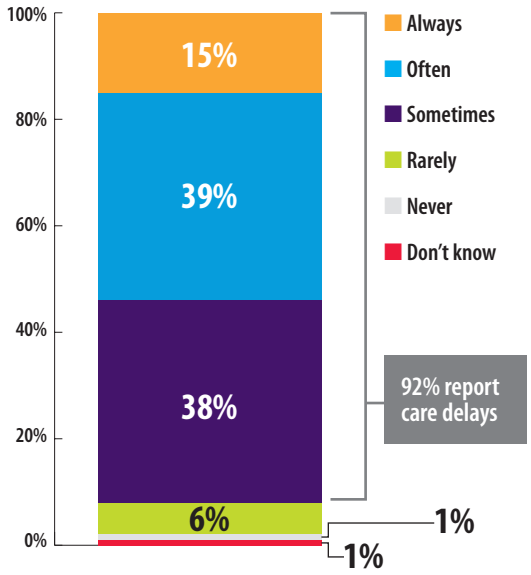
Q: In the last week, how long on average did you and your staff need to wait for a **prior authorization (PA)** decision from health plans?



Total does not equal 100% due to rounding.

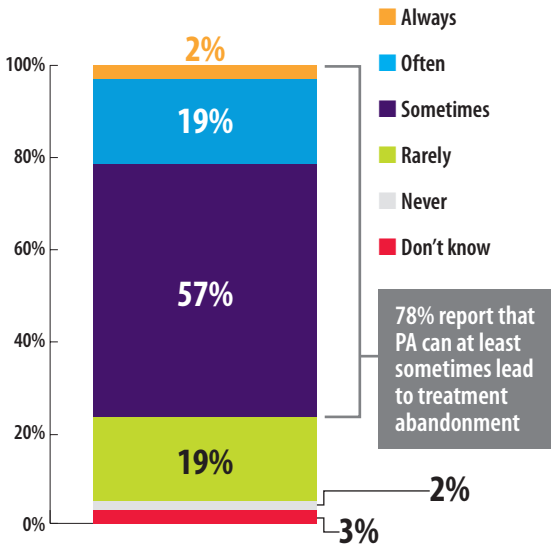
Care delays associated with PA

Q: For those patients whose treatment requires PA, how often does this process delay access to necessary care?



Abandoned treatment associated with PA

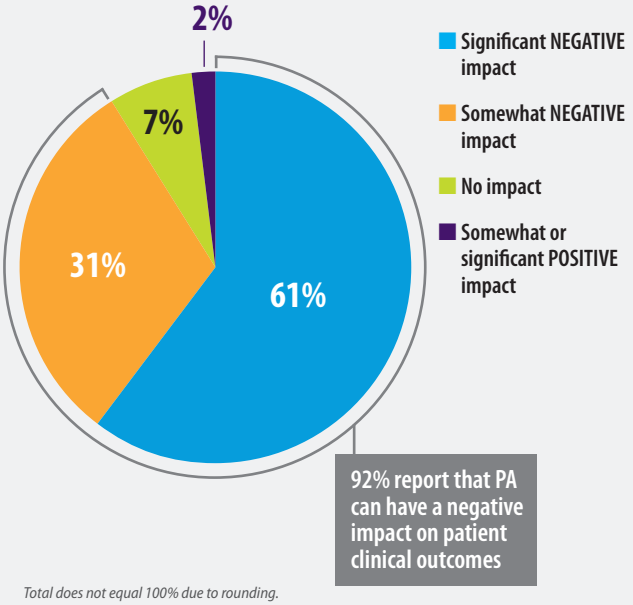
Q: For those patients whose treatment requires PA, how often do issues related to this process lead to patients abandoning their recommended course of treatment?



Total does not equal 100% due to rounding.

Impact of PA on clinical outcomes

Q: For those patients whose treatment requires PA, what is your perception of the overall impact of this process on patient clinical outcomes?

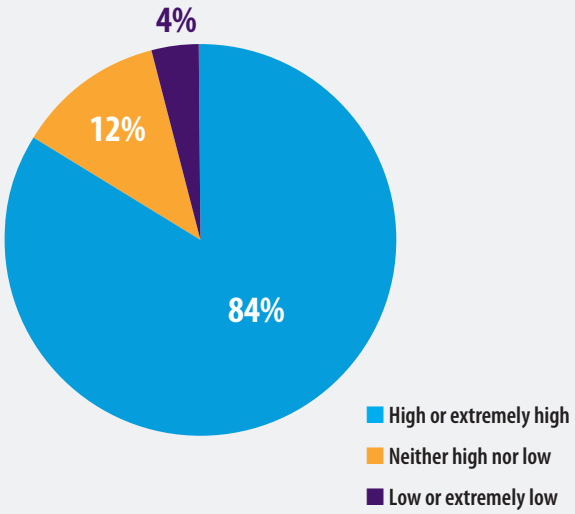


Total does not equal 100% due to rounding.

PHYSICIAN IMPACT

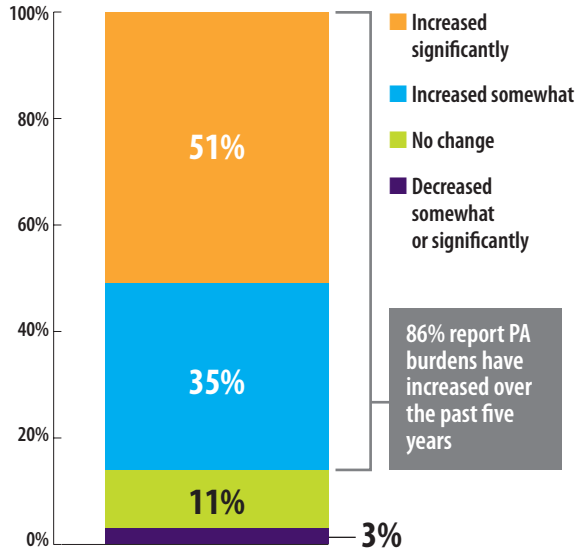
Physician perspective on PA burdens

Q: How would you describe the burden associated with PA for the physicians and staff in your practice?



Change in PA burden over last five years

Q: How has the burden associated with PA changed over the last five years for the physicians and staff in your practice?



Additional PA practice burden findings

Issue	Survey result
Volume	13.9 average prescription PAs per week + 15.1 average medical services PAs per week **29.1 average total PAs per physician per week***
Time	Average of **14.6 hours** (approximately two business days) spent each week by the physician/staff to complete this PA workload
Practice resources	**34%** of physicians have staff who work exclusively on PA
Repetition	**79%** of physicians are **sometimes, often or always** required to repeat PAs for prescription medications when a patient is stabilized on a treatment regimen for a chronic condition

* Total PAs per week rounded after combining prescription and medical services PAs.

Survey questions

Volume: Please provide your best estimate of the number of prescription and medical services PAs completed by *you yourself and/or your staff* for your patients *in the last week*. Do not include PAs that practice staff completed for the patients of other physicians in your practice.

Time: Thinking about all of the PAs you and your staff completed in the last week, please provide your best estimate of the number of hours spent on processing these PAs. Do not include PAs that practice staff completed for the patients of other physicians in your practice.

Practice resources: Do you have staff members in your practice who work exclusively on PA?

Repetition: How often are you required to repeat PAs for prescription medications when a patient is stabilized on a treatment for a chronic condition?

Survey methodology

- 27-question, web-based survey administered in Dec. 2017
- Sample of 1000 practicing physicians drawn from M3 panel
- 40% primary care physicians/60% specialists
- Sample screened to ensure that all participating physicians:
  - Are currently practicing in the U.S.
  - Provide 20 or more hours of patient care per week
  - Complete PAs during a typical week of practice

For information on the AMA's advocacy efforts and resources to reduce PA burdens, please visit ama-assn.org/prior-auth.

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