Washington State Medical Association
WSMA
Physician Driven
Patient Focused

2001 Sixth Avenue, Suite 2700
Seattle, Washington 98121
(206) 441-9762
(800) 552-0612
Fax: (206) 441-5863
Email: wsma@wsma.org

1800 Cooper Point Road SW
Bldg 7, Suite A
Olympia, Washington 98502
(360) 352-4848
(800) 562-4546
Fax: (360) 352-4303

June 17, 2016

Jim Freeburg
Washington State Office of the Insurance Commissioner
P.O. Box 40255
Olympia, WA 98504-0255

Dear Mr. Freeburg:

On behalf of the Washington State Medical Association and its 10,000 physician members across the state, thank you for the opportunity to submit comments in anticipation of rulemaking intended to streamline prior authorization processes so that our patients in Washington receive the right care at the right time.

Prior authorization: a barrier to patient care

Thanks to efforts by the state to increase the number of people covered by health insurance, Washingtonians have an unprecedented selection of health plans from which to choose. Consumers research and shop for plans based upon available coverage of certain medical services and prescription drugs. Unfortunately, after paying the appropriate premiums and meeting other out-of-pocket obligations, but before they can receive care from a physician, consumers are often denied medically appropriate services covered under their plan through a process referred to as "prior authorization."

While the physician-patient relationship is paramount and should not be subject to third-party review, the WSMA understands the need to limit over-utilization. Prior authorization has been a central component of utilization management programs for decades, but in the last few years, health issuers are using the tool at unprecedented rates for an ever-growing array of medical services and prescription drugs. While use of the process has skyrocketed, issuer technology and systems have not kept pace, leaving many physicians and patients to depend on fax machines and 1-800 numbers while navigating a maze of ever-changing criteria and requirements.

A recent survey of physicians and practice managers in Washington state revealed that 72 percent of respondents are "very or extremely concerned" about their practice's ability to obtain prior authorization due to the complexity, variability and lack of transparency surrounding prior authorization requirements, and issuer responsiveness to prior authorization inquiries. While the underlying goal of prior authorization is to limit over-utilization, the survey makes clear that the current environment presents huge administrative challenges for physicians and takes time away from patient care.

We applaud the Office of the Insurance Commissioner (OIC) for seeking to improve patient access to care by addressing administratively burdensome prior authorization processes in Washington state and urge boldness during this rulemaking to strike a critical balance between appropriate utilization of medical services and access to patient care.

In summary, we urge the OIC to utilize existing authority to streamline and standardize various health issuer prior authorization processes in Washington state, by:

- Creating **transparency** around prior authorization requirements.
- Requiring health carriers to review, and approve or deny prior authorization requests in a standardized, **timely manner**.
- **Eliminating** prior authorization requirements **for certain services.**
- Prohibiting retroactive denials of covered, medically necessary services.
- Encouraging **automation** of prior authorization processes via website submission, and adoption of HIPAA transaction standards for prior authorization of healthcare services.
- **Restricting** the use of "step therapy" where there is **possibility of patient harm** and requiring **formulary transparency**.
- **Applying the rulemaking to agents** that conduct utilization review on behalf of an issuer.
- Creating **detailed resources** with clear requirements for providers and issuers, and provide formal **sub-regulatory guidance** when requested.

OIC authority under SB 5346

In 2009 the legislature passed SB 5346 designed to streamline and standardize administrative interactions between issuers and providers. To "address inefficiencies, constrain healthcare inflation and make health care more affordable for Washingtonians," the expressed intent of the legislature is to establish streamlined and uniform procedures for issuers and providers of health care services "by fostering a continuous quality improvement cycle to simplify health care administration" involving leadership in the healthcare industry and regulatory oversight from the OIC.

SB 5346 gives the OIC clear authority to implement through rulemaking the sections of the bill that have not been voluntarily adopted by the industry to date. The provisions related to prior authorization that have not enjoyed industrywide adoption and should be included in the upcoming rulemaking include:

- Sec. 10(1)(a)(i): ensuring issuers do not automatically deny claims for services when extenuating circumstances make it impossible for them to obtain prior authorization before services are performed or notify issuers within 24 hours of a patient's admission.

- Sec. 10(1)(a)(ii): requiring issuers to use common and consistent timeframes when responding to provider requests for medical management approvals (certain elements addressed in part during other rulemakings).

- Sec. 10(1)(b): developing, maintaining and promoting widespread adoption of a single common website where providers can obtain issuer preauthorization requirements (certain elements addressed in HB 1471 from 2015).

- Sec. 10(1)(c): establishing guidelines for issuers to develop and maintain a website that providers can utilize to request preauthorization, including a prospective clinical necessity review, receive an authorization number and transmit an admission notification.

Additional areas for consideration

Definitions in WAC

Definition of "prior authorization"

We encourage the OIC to define "prior authorization" in WAC as broadly as possible, so that it includes any practice implemented by a health issuer, or an agent acting on behalf of the issuer, in which coverage

of a health care service, device, or drug is dependent upon a patient or physician obtaining pre-approval. The definition of prior authorization should include, but not be limited to, preadmission review, pretreatment review, quantity limits, step therapy, utilization, case management, and out of network specialty referrals. Prior authorization should include any utilization review organization's requirement that an enrollee or physician notify the utilization review organization prior to providing a service.

"Utilization review organizations", including issuer agents
Entities that conduct utilization review for services provided to patients in Washington state should be referred to in the WAC as "utilization review organizations" which include insurance issuers licensed to offer, sell, or issue a health plan in the state. The definition should also include agents acting on behalf of an issuer which conduct utilization review and determine certification of admission, extension of stay, or other health care services for Washington residents, or any entity performing utilization review that is affiliated with, under contract with, or conducting utilization review on behalf of, a business entity in this state.

Transparency of requirements
Require critical, common-sense information to accompany denials
An issuer that denies a request for prior authorization should be required to provide the specific reason for the denial. If the request is incomplete, the issuer should be required to indicate the specific additional information that is required to process the request within a reasonable amount of time as determined by the OIC.

Website requirements
HB 1471 from 2015 requires health issuers to "post on their websites and provide upon the request of a covered person or contracting provider any prior authorization standards, criteria, or information the issuer uses for medical necessity decisions" (similar requirements were included in SB 5346). WSMA urges the OIC to take this critical transparency effort a step further by requiring issuers to include on their websites specific documentation that a provider must submit in order for a prior authorization request to be considered complete. Issuers should also be required to list *updated* clinical criteria used to make decisions. Services not requiring a formal prior authorization request, but that are still subject to medical necessity and pre-service criteria, should be included.

In addition, issuers should be required to list updated contact information for the medical officer responsible for issuing prior authorization decisions (on behalf of the issuer or its agent) so that physicians know who to contact to discuss with that party the rationale for denying treatment. This problem presents itself most frequently by issuer agents that do not make this kind of information available.

Communication of new requirements to physicians and other treating providers
Health issuers can frequently amend prior authorization requirements without notifying physicians, leading to incomplete, incorrect or even unnecessary submissions of prior authorization requests. The OIC should require that changes to prior authorization requirements be subject to the same notification requirements under WAC 284-170-421(6)(a-d) and be treated in a similar manner to other amendments to contract, including: requiring issuers to provide at least 60-days' notice to providers and facilities of changes that affect compensation or delivery of health care services; permitting providers and facilities to terminate contracts if they do not agree with changes; allowing providers to reject amendments without impacting the terms of the existing contract; prohibiting retroactive changes to contract without the express written consent of the provider or facility; and, requiring issuers to give providers or facilities full access to the coverage and service terms of the applicable health plan for an enrolled patient.

Timeliness

Frequently, the time it takes an issuer to review and approve a prior authorization acts as a direct barrier to patient care.

Timeline
Per SB 6511 from 2014, the OIC placed timelines for prior authorization review in WAC 284-43-2000. The WSMA supports mandated timelines for prior authorization that allow physicians to provide critical care to patients in an expeditious fashion.

Failure to meet timelines in WAC
If an issuer or its agent fails to meet the timelines in WAC 284-43-2000 for a completed review request, or fails to notify the provider that information needed to conduct the review is incomplete, or if a utilization review organization fails to properly maintain submitted records for which the provider or enrollee has documentation of submission, the service should be deemed approved.

Eliminate prior authorization requirements for certain services
Prior authorization for low-cost, high-value treatments, such as generic drugs, should be eliminated.

Focus should be on outliers
The OIC should implement policies that require health issuers to focus on outliers – those who order tests or utilize services that are not consistent with similar clinical circumstances as opposed to physicians that have a proven track record of appropriate utilization.

Appropriate use criteria
Services for which appropriate use criteria exist should be exempt from prior authorization requirements if the provision of the service comports with applicable criteria. Where appropriate use criteria exist, the services also should be exempt from retrospective review.

Prohibit retroactive denial of covered, medically necessary services
The OIC should ensure that once a prior authorization has been secured, a health issuer is not able to retroactively deny coverage for the service. The presumed availability of coverage for a particular service, based on that prior authorization, directly influences the course of treatment agreed upon by the patient and the provider. When health issuers retroactively rescind a prior authorization, patients can be left bearing the financial responsibility for services provided to them by physicians that were understood to be approved and should otherwise be covered under the health plan.

Prohibit retroactive denial of covered, medically necessary services provided intraoperatively
Surgeons can request prior authorization for a specific procedure and receive the approval. However, during the actual surgery, the surgeon may discover that an alternative surgical procedure is clinically necessary. As example, one physician recently noted that during surgery for a vestibular stenosis repair, he had to harvest auricular cartilage because the patient did not have enough septal cartilage. Even though the report clearly documented medical necessity, and that the decision to harvest a different kind of cartilage was made intraoperatively, the service was denied retroactively.

In instances like these, issuers deny payment for the procedure performed as it differs from the procedure initially authorized, and do not typically allow for retroactive corrections to these situations.

These kinds of denials are not unique to surgery. A primary care provider (PCP) may request an imaging study, and can provide a CPT code as part of the prior authorization request. The radiologist may decide, appropriately, that a different study, rather than the one ordered by the PCP, be performed and that alternative study can have a different CPT code than what was initially stated.

Issuers typically do not offer any latitude in this difference, nor will they offer retroactive correction to this difference in codes. These kinds of denials should be prohibited.

Clinical criteria
While current WAC states that "each issuer must maintain a documented utilization review program description and written clinical review criteria based on reasonable medical evidence," issuers' criteria vary widely, suggesting that issuers are not basing their decisions on medical based evidence.

So that physicians and issuers alike are making decisions based on the most current consensus of medical literature, issuers should be required to utilize the most recent, nationally-accepted, evidence-based appropriate-use criteria or clinical guidelines produced by national specialty societies and nationally recognized utilization management organizations.

Health issuers should be required to make criteria available to physicians upon request.

Reviews and appeals
Prior authorization reviews conducted by physicians licensed in Washington
To ensure a fair process for patients, a physician (or any person with authority over decision-making) who is conducting prior authorization and utilization reviews and making decisions about the care that Washingtonians receive should be licensed to practice medicine in Washington state.

In addition, reviews should be conducted during the business hours where the patient is located, not where the issuer or agent is located.

Require consultation before prior authorization denials
Patients and physicians can be subject to cumbersome prior authorization processes, only to receive a denial for medically necessary services. At that point, the patient and physician have little recourse other than forgoing the service, starting the process over, or tracking down the utilization review physician, which often proves challenging.

The OIC should require health issuers to notify the requesting provider when medical necessity is being questioned, prior to issuing a denial. The provider should have the right to discuss the medical necessity of the health care service with the utilization review physician. This requirement would obviate the need for patients to forgo clinically indicated or even critically necessary services, and for physicians to re-engage in an administratively burdensome process only to meet the same end result.

Appeals process
Each issuer should be required to have an appeals process for situations in which a physician disagrees with the determination of a prior authorization request. The appeal process should be completed within a timeframe considered reasonable by the OIC.

Require capability to submit prior authorization requests electronically
Website submission
The OIC should require development of a *single* website that all issuers must utilize to facilitate prior authorization requests from physicians in Washington state. The website should allow physicians and hospitals to receive authorization numbers and transmit admission notifications and should provide for secure electronic transmission using standards established by the Council for Affordable Quality Health (CAQH) on operating rules for information exchange.

While the creation of a single website would not be a "silver bullet" solution to the current antiquated administrative process, it would at least obviate the need for 1-800 numbers and fax machines.

HIPAA standard ASC X12N 278
We urge the OIC to require issuers to submit documentation certifying that their data and information systems support ASC X12N 278 HIPAA transactions for preauthorization of health care services. Requiring all health issuers in Washington state to offer the ability to submit preauthorization requests through the transaction would place Washington's healthcare system at the forefront of a solution that may truly streamline the prior authorization process and make it easier and less costly to seek approval for covered services.

While some issuers currently offer web portals as an electronic means to submit preauthorization requests, physicians and practice staff must navigate to each issuer's webpage, obtain log-in information and learn to operate each unique system. These portals do not represent industry standardization sought under SB 5346.

Utilization of HIPAA standard ASC X12N 278 has the potential to allow providers and issuers to securely manage utilization at the point of care through existing practice workflows. Unfortunately, according to the CAQH, only 10 percent of health plans have adopted the standard. According to CAQH, "given the apparent lack of adoption by health plans of fully electronic transactions to support submission of prior authorization attachments, healthcare providers may currently have no alternative to web portals and manual processes as a means of submitting prior authorizations."

Limit requests for medical records
When performing prior authorization, a health issuer should only be permitted to request a patient's medical records when a legitimate difficulty develops in determining the medical necessity or appropriateness of the health care service. The issuer should only be allowed to request access to the necessary and relevant sections of the patient's medical record.

Alternative Compliance Arrangements
The OIC should protect the ability of issuers and providers to enter into innovative contractual arrangements that allow mutually agreed-upon alternatives to prior authorization processes. Such arrangements help to ensure services are provided to patients in accordance with the issuer's clinical and pre-service requirements in a timely manner.

Prescription drugs
Step therapy
Step therapy is intended to control healthcare costs but can act as a barrier between patients and the needed medication that physicians prescribe for them. These barriers can have detrimental impacts on patients. For example, an asthma patient that is stabilized on a particular medicine may be required by the issuer to undergo drug step therapy (also known as "fail first" therapy). These patients can become unstable and end up in the emergency department. For psychiatric patients, this might mean the difference between leading a stable life and going to jail or living on the street. The issuer's desire to control costs should not endanger the health or safety of the patient.

The OIC should consider restricting the use of step therapy where there is a possibility of patient harm.

Also, once a patient has completed step therapy, the issuer should not be able to require additional step therapy for the same condition.

Prior authorization for duration of enrollee's contract term
Any authorization for a prescription drug should remain valid for the duration of an enrollee's contract term, provided:

- the drug continues to be prescribed for a patient with a condition that requires ongoing medication therapy
- the drug has not otherwise been deemed unsafe by the Food and Drug Administration (FDA)
- the drug has not been withdrawn by the manufacturer or the FDA

Formulary changes
To minimize disruption at the end of a contract year, issuers should be required to give patients 60-days' notice of an upcoming change in their formulary, so that the patient has adequate time to meet with their physician and identify alternatives.

Formulary transparency
Issuers should have easy access to drug formularies on issuer websites, with access to patient-specific formularies with their identification number.

Require critical, common-sense information to accompany denials
If a prior authorization request is denied, issuers should provide physicians with approved medication alternatives in the same therapeutic class. Otherwise, the prescribing physician could be required to guess – and possibly guess incorrectly – which alternative medication(s) the issuer would approve.

Transparency
Reporting
Issuers and their agent's prior authorization processes are shrouded in mystery. While countless anecdotes from physicians and patients exist that highlight barriers to care, the OIC and policymakers require data to better understand the burden that utilization management imposes. Issuers should be required to provide data regarding each of the following categories of requests: non-urgent preservice review requests, immediate review requests, concurrent care review requests, post service review requests, and urgent care review requests for both medical service and pharmacy benefits. Those data should address:

- Total number submitted
- The number and rate of approvals
- The number and rate of denials
- The number and rate of immediate review appeal approvals
- The range and average time from receipt of completed request to notification of decision
- For appeals, the range and average time from receipt of completed appeal request to notification of decision

Enforcement
It is unclear at this point whether there would be any penalty imposed on health issuers for failure to comply with the finalized prior authorization requirements established through the anticipated rulemaking. We recommend that the OIC develop standards in order to ensure best application of the rules. We argue that the establishment of uniform standards for failure to comply with the rules would be a preferred and much more effective alternative than requiring that patients and physicians file individual situation-specific complaints with the OIC.

Need for sub-regulatory guidance from the OIC
Prior authorization is currently governed by a maze of RCWs and WACs, making it very confusing to understand what, exactly, is required of issuers and physicians. Once requirements are finalized, the WSMA calls on the OIC to create and make available detailed resources with clear requirements, and provide formal sub-regulatory guidance when requested.

The implementation of the Affordable Care Act was a herculean effort of which the OIC should be proud. Now that so many more Washingtonians have coverage, it is critical that the OIC ensure consumers are receiving the care promised through the health plans that they have purchased. We applaud the OIC for seeking to improve patient access to care by addressing administratively burdensome prior authorization processes in Washington state and again urge boldness during this rulemaking.

We appreciate your consideration of these comments. For questions, please do not hesitate to contact Jeb Shepard at jeb@wsma.org.

Sincerely,

Jennifer Hanscom, Executive Director/CEO

Ray Hsiao, MD, President

cc: WSMA Executive Committee
Kathryn Kolan, JD, Director, Legislative and Regulatory Affairs