

June 17, 2106

The Honorable Mike Kreidler
Insurance Commissioner
State of Washington
PO Box 40255
Olympia, WA 98504-0255

Dear Commissioner Kreidler:

On behalf of the Seattle Cancer Care Alliance (SCCA), we want to thank you for providing the opportunity to comment on the prior authorization rulemaking being undertaken by the Office of Insurance Commissioner's (OIC).

The SCCA is the only National Cancer Institute (NCI) Designated Comprehensive Cancer Center in the Pacific Northwest. The SCCA partners with the Fred Hutchinson Cancer Research Center, Seattle Children's Hospital and University of Washington Medicine to provide our patients with access to cutting-edge cancer treatment and the latest innovations in cancer care. Together with our partners, our mission is the pursuit of better, longer, richer lives for our patients. We have some of the best clinical outcomes in the region and in the country, and are driving pioneering changes in how cancer is treated—extending lives and even finding cures.

As we've discussed previously, one significant barrier we face in the realization of our mission is the fact that many patients who could benefit from this level of care do not have access to it. Changes in the health care market, as well as barriers in federal and state law and regulation, have combined to limit our ability to disseminate the cancer advances—many of which are funded by the federal government—that distinguish us as an institution.

Since the implementation of the Affordable Care Act we have noted that issuers have increased their use of prior authorization processes to control utilization and limit access to medically necessary specialty services. In addition, with the advent of "narrow" or limited provider networks, issuers have established onerous "out-of-network" benefit level exception processes that are particularly burdensome for specialty providers.

Despite the success of the Affordable Care Act (ACA) in expanding coverage to millions of Americans, many insured individuals face barriers to receiving the highest quality cancer care. This is because issuers limit patient access—either as a way to avoid adverse selection or to offer low-cost narrow networks to consumers—a growing trend. Often, consumers are not aware that SCCA is not included in their network, or is only included for very narrow services such as second opinions.

Prior to the passage of the ACA, the SCCA was part of virtually every network offered in Washington State. After implementation of the ACA, the SCCA noted a disturbing trend in the Exchange and other commercial insurance, as issuers modified their plan designs and networks to control their risk exposure. The issuers either chose not to contract with SCCA or provide only limited access following an arduous prior authorization process or greater patient out-of-pocket costs. Being out of network creates significant barriers for our patients and extraordinary administrative expense for our facility.

Please consider the following points during the rulemaking to streamline the prior authorization process:

Scope of Rulemaking Including Current Rules:

- The OIC should recognize that prior authorization requirements are part of the overall utilization management practices for health issuers and are currently subject to the standards in place for WAC 284-43-2000. Because the current rule incorporates prior authorization requirements, including timelines for response, we urge the OIC not to add a separate and distinct layer of rulemaking.

Prior Authorization of Specialized Treatment and Clinical Trials:

- Certain new and highly specialized treatment or clinical trials may fall outside of the issuer's typical medical necessity protocols or may still be considered to be "experimental" or "investigational" if the issuer does not update the protocols to recognize emerging therapies and treatments. This often leads to time consuming appeals and delays in treatment. Although SCCA does not advocate for the use of unproven therapies, it is important to have standards and processes in place to authorize cutting edge therapies when they are available. The OIC should review the prior authorization standards set forth in WAC 284-44-043; WAC 284-46-507 and WAC 284-96-015 and consider modifying and incorporating these sections in its current rulemaking.
- At a minimum for the treatment of cancer, the medical necessity criteria should be based on the Federal Drug Administration (FDA) approved indications or National Comprehensive Cancer Network (NCCN) category 1 and 2A recommendation for cancer diagnosis. NCCN has evidence based guidelines for cancer diagnosis and treatments and although Medicare follows NCCN guidelines, some issuers routinely deny medically necessary treatments approved and recommended by the FDA or the NCCN 1 and 2A recommendations.
- The current OIC rule WAC 284-30-450 addresses off-label use of certain drugs and should serve as a starting point for off-label drug use, but it may not be consistently followed by issuers in the market. SCCA requests that this rule be updated and those standards be adopted and enforced for expedited review of treatments or services for rare or aggressive cancers and unique situations where standard treatments/guidelines are not available. Many issuers will approve these types of requests when it's appealed but it is very labor and time intensive with long delays. It can take 30 days or longer for the appeal process and patients often times cannot wait that long for a decision.

Issuers Refusing to Conduct Prior Authorization Review:

- Appropriate prior authorization requirements do provide a level of protection for the patients and providers by assuring that the services are medically necessary and covered under the health benefit plan. After the Washington state legislature passed RCW 48.43.525 in 2000, many issuers eliminated prior authorization requirements in order to avoid the prohibition of retrospective denial at the time of claim payment. Some payors will not allow prior authorization review and then will deny payment for the treatment or service after it has been provided by determining that it was not medically necessary. This type of denial can result in unexpected out of pocket cost to patients. Although SCCA is not advocating that every service or procedure be subject to prior authorization it encourages the OIC to engage with stakeholders to determine how to strike a balance between the administrative burden of prior authorization and providing meaningful and reliable assurances to patients and providers that the proposed treatment will be covered by their health benefit plan.

Out-of-Network Referrals:

- Prior authorization procedures should include out-of-network benefit level exceptions that are required when the services are not available from an in-network provider. Further, the authorization should be all inclusive rather than a multi-step process for each procedure or treatment. Some issuers require that the out-of-network process be completed each time the patient requires specific services.
- Out-of-network benefit level exception prior authorization should allow in-network benefits for all cancer patients who are interested in the evaluation of a clinical trial as well as participation in a trial when one is not available within their network. NCCN guidelines recommend clinical trial participation as a treatment option for various cancers.
- Prior authorization processes, especially for out-of-network exception specialty care should take into consideration the need to integrate the testing and treatment of the patient. If the patient is authorized to receive treatment at a specialty center, then all the necessary tests and treatment should be authorized to be performed by the specialty center. SCCA is sometimes required to use the previous results from tests and imaging performed by non-SCCA providers or to refer our patients to in-network providers for follow up testing or imaging, even though the patient is under our care. Often these tests or images need to be repeated due to quality issues, driving up the cost of care.

Access to the Issuer's Medical Director and Health Care Experts and Submission of Medical Records:

- Prior authorizations for certain services or treatment may be fairly straightforward and easily handled through an automated system by non-medical professionals. Other more specialized care may require the referring or receiving provider or facility to interact directly with the issuer's Medical Director(s). The OIC should explore ways to streamline this type of interaction and assure that the issuer provides access to and timely responses to requests for authorization for medically necessary specialty services. In addition, issuers should ensure that the medical information is reviewed by individuals with the appropriate specialization and board certification.

- Automated prior authorization processes should be capable of easily transmitting medical information including large digital files, and not require labor intensive preparation or conversion of medical records. In other words, any system should not increase the administrative workload of the provider's staff.
- Automated prior authorization systems must be secure and comply with HIPAA patient confidentiality requirements.

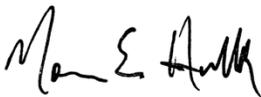
Prior Authorization and Utilization Management by Issuer's subcontractors:

- If the issuer sub-contracts its network or utilization review including prior authorization processes, the rule must apply to the sub-contractor. In addition, and standard treatment protocols utilized by the issuer or sub-contractor as part of the prior authorization process should be made available to the patient and provider upon request.

In closing, the SCCA wishes to thank you for the opportunity to submit these preliminary comments. We look forward to working with the OIC and other stakeholders as the proposed rules are developed and available for review.

If you should have any additional questions, please feel free to contact me at (206) 288-1051.

Sincerely,

A handwritten signature in black ink, appearing to read "Norman E. Hubbard". The signature is fluid and cursive, with the first name being the most prominent.

Norman E. Hubbard
Executive Vice President
Seattle Cancer Care Alliance