March 16, 2022

By electronic submission

The Honorable Micky Tripathi
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C Street SW, 7th Floor
Washington, D.C. 20201

Re: UCSF Center for Digital Health Innovation's Comments on *Request for Information: Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria*

Background: UCSF and the UCSF Center for Digital Health Innovation

UC San Francisco is a worldwide leader in health care delivery, discovery, and education, with a mission of "Advancing Health Worldwide." In recent years, we have invested heavily in developing the information technology resources to help health care providers, patients, researchers, innovators, educators, and students have the interoperability and tools needed to succeed in the rapidly evolving digital age. UCSF's medical centers consistently rank among the nation's top hospitals, according to U.S. News & World Report, and see approximately 43,000 hospital admissions and 2.4 million outpatient visits annually, including care of the county's underserved and Northern California's veteran populations. UCSF focuses on solving real and important problems at regional, national, and global levels. UCSF's own scope extends beyond tertiary/quaternary care at UCSF Health facilities, to our level one trauma center at Zuckerberg San Francisco General Hospital, the safety net hospital for the City and County of San Francisco, to the San Francisco Veterans Affairs Medical Center; and to affiliate network including community hospitals and clinics across the nine-county Bay Area. Additionally, through UC Health, we have access to 15 million patient health records at six academic medical centers across California, representing an incredibly diverse set of individuals and approximately one-third of California's population in the world's fifth largest economy. At UCSF we have played a seminal role in developing precision medicine, an emerging field that aims to harness vast amounts of molecular, clinical, environmental, and population-wide data to transform the future of health diagnosis, treatment, and prevention for people worldwide. UCSF research has spawned more than 185 startups and helped establish the Bay Area as the nation's premier biotech hub.

In 2013, UCSF founded its Center for Digital Health Innovation (CDHI), which works to create effective digital solutions that transform health and enable compassionate care delivery for all. At CDHI, our mission is making better health accessible to everyone, everywhere. Our work focuses in three areas: (1) Putting patients in the driver's seat as their partner in care, delivering a care experience that is unique to the patient; (2) Making it possible to deliver exceptional and scalable healthcare everywhere, without borders or boundaries; (3) Aligning the best of human and machine intelligence to deliver the next generation of care.

UCSF's Center for Digital Health Innovation (CDHI) is pleased to respond to the Office of the National Coordinator's Request for Information on *Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria*, 87 FR 3475.

Patient Journey and Use Case-Driven Implementation

At the UCSF Center for Digital Health Innovation, we strongly support the development of improvements in the electronic prior authorization process. Given our lived experiences in the delivery of care to a wide

spectrum of patients and communities, we wish to comment on the approach and perspective of this critically important and valuable work, in the hopes of further supporting and stimulating successful outcomes.

Prior authorization is a topic of great importance to us at UCSF. As we will describe below, the current situation with prior authorization is untenable. Patients are routinely frustrated, waste hours and days battling the system, and worse, have frequent delays in basic care needs. Providers and clinical staff waste precious time completing paperwork instead of spending time with patients. Clinics and hospitals spend significant resources on hiring additional staff to deal with the paperwork burden, inhibiting our ability to put those resources to better use. The systems, with layer upon layer of middlemen and ever-changing rules and processes, have become so complex that we are often left uncertain of what the process is, what the next step is, what the rules of the game are, or who is currently holding the baton in what is much more of a maze through an American Gladiators course than a 4x100 relay race. To all who suffer the consequences, it often feels like intentional denial of care is the goal. At a time when healthcare costs are spiraling upwards, patients are frustrated by a poor care experience, and healthcare workers are leaving the workforce in record numbers due to burnout, one only need to look at prior authorization as a prime example of a system in need of reform.

Given our frustration, disappointment, and even dismay, we are eager and enthusiastic about the ONC's willingness to tackle prior authorization. The development and deployment of technical standards is necessary to support improvements in patient care, patient experience, and provider experience. At the same time, technical standards, while necessary, are not sufficient to heal all that ails prior authorization. Often when a manual process is digitized, as we have seen in the shift from paper medical records to electronic health records, the inefficiencies in the system are exposed, not eliminated. What was once invisible becomes visible. We expect that successful deployment of technical standards into prior authorization would do the same. The real drivers of the burdens on patients and providers – the volume of authorizations, frequency of denials, delays in approvals, ever-changing requirements and rules – would be exposed. As this work gets underway, we therefore encourage ONC to coordinate with other federal agencies to work toward comprehensive prior authorization reform.

As standards are developed and tested, we believe it is critical to their success that they be driven by real world use cases and centered around patient and provider experience and workflows. As was commented on at the March 10, 2022 HITAC Meeting, the work of the Electronic Prior Authorization Standards Task Force could easily become unachievable and mired in complexity if it becomes overly focused on technology. In our experience, we have seen many initiatives that overly focus on technology but fail to achieve important improvements in care delivery outcomes or experiences. While we are certain this initiative's stakeholders and project sponsors have the right motivations, if all stakeholders are not centered around a specific future state workflow or outcome that they are trying to achieve, a series of technology standards may fail to result in any particular outcome.

Therefore, we suggest that the Electronic Prior Authorization standards be anchored by a core set of patient-centered journeys and targeted clinical care outcomes. That is, what specific outcome should a patient be able to accomplish tomorrow that they were not able to do today, and what system changes and technology standards are needed to support that specific outcome? Which actors need to be involved and which underlying systems need to be developed to support an end-to-end workflow? And, in a future where AI-driven automation is increasingly feasible, reducing the burden of human intervention, will the electronic standards support and enable this future state? ONC has already proposed an excellent set of functional capabilities to be considered. We suggest that the ONC broaden that set of required capabilities, and ensure that as the work is completed, each tranche of work attempt to solve for a single end-to-end patient use case, as opposed to solving for individual fragmented capabilities.

Example Use Cases

Diabetes Care: Durable Medical Equipment Authorization

People with type 1 diabetes rely on devices like insulin pumps and continuous glucose monitors for their most basic care needs – to stay in good health minute-by-minute by continuously monitoring their blood glucose levels and administering insulin that their bodies no longer produce. Inability to perform these basic tasks can become immediately life threatening. Access to continuous glucose monitoring devices is considered basic standard of care for type 1 diabetes by all major professional associations. Despite this, payors have a wide variety of clinical and documentation requirements that must be met in order for patients to receive these medical supplies. In attempting to have continuous, uninterrupted access to these life-sustaining supplies, people with diabetes endure several challenges. First, their insurance plans may change from year to year or when they have a change in life circumstance, meaning they have a sudden need for a new authorization with new requirements. Second, because these supplies are often obtained through a durable medical equipment benefit, the process is opaque, with no electronic prescription process as there is to pharmacies, no way for the patient or provider to see the status, and manual paperwork (most often paper and fax) requested by the durable medical equipment suppliers. Third, authorizations expire, and those expiration events are often invisible to the patient. Fourth, patients do not have transparency into the expected share of cost for these supplies.

On the provider side, the process is also complex. First, providers are blind to what device is or is not covered by an individual patient's payer, whether the payer has requirements about which supplier must be used, and whether the payer has authorization requirements. Second, providers are often asked to create log-ons and go to payor or DME vendor web portals or applications in order to send information. Since an individual provider will see patients across dozens or hundreds of these, this is untenable. Instead, in the future, the information must become transmittable from the provider's "home" EHR or health IT system, just as is done today with electronic medication prescribing. Third, requests for documentation are most often paper-based and require faxes back and forth. In particular, this is untenable in a telehealth-based world, where providers are no longer working from a physical clinic location, and thus a paper-based workflow cannot function. At UCSF, we have resorted to scanning faxed paperwork into Docusign to send to providers to sign, and then fax back to the payers and suppliers. Even with this workaround, some payors refuse to accept an electronic signature, and demand that a wet signature be obtained.

The currently proposed technology standards and capabilities by ONC, while necessary, are *insufficient* to resolve the common use case described above. We seek an end-to-end solution for the patient and provider that allows for a paperless, transparent ability for a provider to prescribe a diabetes device, see the patient's share of cost estimate, electronically submit from their EHR (or have submitted in automated fashion) the necessary supporting documentation, receive a response with transparency into the reason for the response, and have transparency into expirations.

Therefore, we recommend a use case for the Electronic Prior Authorization implementation that enables the above Durable Medical Equipment end-to-end workflow and outcome for the patient, including:

1. Electronic prescription to be sent from a provider EHR to a durable medical equipment supplier
2. Identify within the DME prescription process when a prior authorization is needed for the item
3. Query a payer API for prior authorization requirements for each item
4. Identify in real time the specific rules and documentation requirements for each item
5. Query a payer API for share of cost estimates for each item
6. Identify in real time the share of cost estimate to the Patient and Provider
7. Collect clinical and administrative documentation needed to complete prior authorization

documentation (electronic forms or templates) directly from the provider health IT system
8. Electronically submit completed documentation for prior authorization to a payer's API, along with supporting information
9. The Provider's health IT system receives a response from a payer regarding approval, denial (including a reason for denial), or need for additional information
10. The Patient receives a response from a payer regarding approval, denial (including a reason for denial), or need for additional information
11. Query a payer's system for updates on a pending prior authorization request and have a reason returned as to why a request is still pending;
12. Payer system identifies when a current authorization is expiring and sends an advance notice to the Patient and Provider
13. Patient or Provider can request a renewal of the existing authorization, leveraging the same above process

Inflammatory Bowel Disease Care: Specialty Medication Authorization

People with inflammatory bowel disease (IBD) - Crohns Disease and Ulcerative Colitis - will carry their diagnosis during the most productive years of their life. If the disease is treated early and appropriately, they will remain in remission, avoid expensive hospitalizations and surgery, and avoid disability – allowing them to have a productive work and family life. This often requires monoclonal antibodies (called biologic medications) be injected subcutaneously or infused intravenously at regular intervals, between every 2 to 8 weeks, and missing even a single dose can lead to the development of anti-drug antibodies and rejection of an effective therapy. Said plainly, if a patient misses even one dose, the medication keeping them healthy may never again be clinically effective for them. Patients may then need to move to the next tier (and often more expensive) therapy, first requiring expensive tests, hospitalizations, and even surgeries. And of course, there are only so many IBD medications available, so a patient cannot continue to jump from one to the next.

In practice, there often appears to be a disconnect between pharmacy benefits and medical benefits that leads to ignorance of this clear and well-documented association between disease remission and reduction in healthcare costs. A particular contracted pharmacy benefit manager (PBM) can have opaque or infrequently updated guidelines, leading to non-adherence to accepted standards of care or acknowledging Food and Drug Administration (FDA) approved therapies. One of the signatories (Dr. Mahadevan) has had peer-to-peer authorization calls where she was told that an FDA-approved medication could not be given to the patient as it was not on the insurance company list yet.

How does this look in our gastroenterology practice? The physician will see a patient with IBD and recommend a biologic therapy. Before the patient can get the therapy, the practice must obtain prior authorization. In nearly every case, that authorization is denied and we must file an appeal – for an FDA-approved therapy given at an FDA-approved dose for an FDA-approved indication! If we are fortunate, the biologic will get approved at this initial appeal stage. Most often, we get another denial and must do a peer-to-peer phone call, interrupting our clinical schedule and patient care to adhere to the availability of the reviewer. We may get a response that we have not tried certain therapies prior to prescribing the biologic. However, these therapies may not be FDA-approved (!) for the indication of IBD (e.g. azathioprine or methotrexate) or they may be ineffective for the severity of disease (e.g. mesalamine). Sometimes we are asked to step through one biologic to get to another. This may be a biologic that is ineffective and not recommended in the American Gastroenterology Association (AGA) guidelines for care (e.g. adalimumab for ulcerative colitis). Other times, medically appropriate and necessary dose increases, based on serum

drug concentration measurements, may be approved for years and then suddenly denied, as has been happening with a medication called adalimumab.

The net result is that in our experience, from year to year, payor to payor, pharmacy benefit manager to pharmacy benefit manager, it is completely unpredictable, opaque, and inconsistent as to which medications are approved. To deal with this administrative burden, our practice employs three full-time staff whose sole role is obtaining prior authorization. On top of this we spend hundreds of hours of nursing and physician time per year for appeals, and it is still not enough, as our patients sometimes end up not receiving their medications. Many community gastroenterology practices have decided they cannot care for patients with complex Inflammatory Bowel Disease because the practices cannot provide the administrative support to obtain all the necessary authorizations, forcing these patients to either not receive therapy or travel great distances to a university center that will see them. We imagine that other clinical areas that prescribe specialty medications – eg rheumatology, neurology – likely experience something similar.

The above frustrating and unconscionable situation persists in large part due to the opacity of the process. Across a large delivery system like UCSF Health, this extra staff, nurse, and provider time spent on arduous, confusing, obfuscated, inconsistent, manual processes pull countless hours of precious resources away from where it is actually needed – in the direct care of the patients, families, and communities we serve. We believe that bringing visibility and bidirectional electronic data transmission will bring much needed transparency to this process, enabling our patients to get the care they need and deserve.

Therefore, we recommend a use case for the Electronic Prior Authorization implementation that enables the above Specialty Medication Authorization end-to-end workflow and outcome for the patient, including:

1. Electronic prescription to be sent from a provider EHR to a specialty pharmacy
2. Identify within the specialty medication prescription process when a prior authorization is needed for the item
3. Query a payer API for prior authorization requirements for each specialty medication
4. Identify in real time the specific rules and documentation requirements for each specialty medication
5. Query a payer API for share of cost estimates for each specialty medication
6. Identify in real time the share of cost estimate to the Patient and Provider
7. Collect clinical and administrative documentation needed to complete prior authorization documentation (electronic forms or templates) directly from the provider health IT system
8. Electronically submit completed documentation for prior authorization to a payer's API, along with supporting information
9. The Provider’s health IT system receives a response from a payer regarding approval, denial (including a reason for denial), or need for additional information
10. The Patient receives a response from a payer regarding approval, denial (including a reason for denial), or need for additional information
11. Query a payer's system for updates on a pending prior authorization request and have a reason returned as to why a request is still pending;
12. Payer system identifies when a current authorization is expiring and sends an advance notice to the Patient and Provider
13. Patient or Provider can request a renewal of the existing authorization, leveraging the same above process
14. A standardized process across insurance providers so that those applying for authorizations can streamline their workflows

In both the diabetes use case around durable medical equipment, and the gastroenterology use case in specialty medications, we look forward to a future where January rolls around, bringing with it plan year changes, and our patients no longer need to take days off of work to spend on the phone fighting for their needed medical treatments, and our office staff and physicians are not buried under mountains of paperwork.

Orthopedic Surgery Care: Procedure Authorization

People who require an orthopedic surgery like a hip or knee replacement require a similar and complex workflow as per any other interventional specialty. As noted above in the other use cases, the surgical pre-authorization workflow requires a complex set of submissions, protocols, and procedures, the combination of which are at best a maze of opacity and complexity, and at worst, appear to patients and doctors as though they are designed to deny care. A recent example that has become a national issue has to do with pre-authorization of robotic total knee surgery. Despite 15 years of data from multiple centers and state registries documenting not only improved outcomes but also decreased 90-day costs of care following robotically assisted surgery (private and public, across the US), some insures are denying care citing that the procedures are "experimental". A closer look shows that a national radiology benefits provider to whom insurers have outsourced pre-authorization has identified the required pre-operative imaging as something they could deny with an associated cost savings in radiology expenditures even if the overall cost of care will be higher. These types of competing interests are symptomatic of a broken pre-authorization system in which agents with competing interests can adversely impact the process, and where lack of transparency allows for obfuscation, delays, and confusion.

We have other stories of where this process is broken but little is more compelling than taking a step back and looking at the big picture. A jarring statistic - *approximately 10% of our operative cases at UCSF Orthopedics are cancelled at the last minute due to a lack of authorization*. Moreover, on appeal or following further data submission, nearly all of these are eventually approved. The issue is not that patients don't qualify or that they do not meet authorization criteria. The issue is that the system for satisfying these criteria is so poorly designed that it causes frequent delays in care. Sometimes, surgical cases are performed without prior authorization with a procedural override. In these cases, more than 90% are eventually retroactively approved! And, of the surgical cases that go through with authorization, approximately 10% require a last-minute flurry of activity and fax exchanges, phone calls, and clarifications that require a massive investment of time and resources before they too are actually approved. The delays in care and systemic costs are jarring when one considers the number of resources required in both provider and payor organizations to manage this wasteful, inefficient process.

Therefore, we recommend a use case for the Electronic Prior Authorization implementation that enables the above Procedure and Surgical Authorization end-to-end workflow and outcome for the patient, including:

1. Ability to identify within the procedural scheduling process when a prior authorization is needed
2. Ability to query a payer API for prior authorization requirements for each procedure, ensuring that the payer information is clear, accessible, and transparent.
3. Ability to identify in real time the specific rules and documentation requirements for each procedure
4. Ability to identify the other authorizations that may be needed as part of the bundle of care related to each procedure
5. Ability to query a payer API for share of cost estimates for each procedure
6. Ability to identify in real time the share of cost estimate to the Patient and Provider
7. Ability to collect clinical and administrative documentation needed to complete prior authorization documentation (electronic forms or templates) directly from the provider health IT system
8. Ability to electronically submit completed documentation for prior authorization to a payer's API, along with supporting information
9. Ability for the provider's health IT system to receive a response from a payer regarding approval,

denial (including a reason for denial), or need for additional information
10. Ability for the patient to receive a response from a payer regarding approval, denial (including a reason for denial), or need for additional information
11. Ability to query a payer's system for updates on a pending prior authorization request and have a reason returned as to why a request is still pending

Government Action Recommendations

The UCSF Center for Digital Health Innovation thus recommends:

1. As Electronic Prior Authorization standards and system certifications are developed and deployed, the above core use cases – end-to-end workflows to support patients receiving needed durable medical equipment, specialty medications, surgical procedures, and others that may be identified – should be used to identify the target state, anchor planning and execution, and to measure success.
2. Electronic prior authorization standards and workflows should also envision and enable a future where automated systems, leveraging machine readable data, are able to directly interact with each other and take humans out of the loop.
3. Electronic Prior Authorization standards should enable users to transparently identify within the prescribing process (within the EHR) what is on formulary, what patient share of cost would be, and when a prior authorization is required.
4. The Electronic Prior Authorization process should immediately and transparently identify what prior authorization requirements are, so that physicians can provide the right information on the first submission (rather than guessing what the insurer or PBM wants to know and getting an immediate rejection for failing to send the right information).
5. Ensuring that the Electronic Prior Authorization submission processes integrate into EHR products and workflows, and are not proprietary, standalone products that require separate logins for different insurers, and also do not require going to any separate websites to review formularies, prior authorization requirements, etc.
6. Ensuring that Electronic Prior Authorization processes seamlessly integrate regular drug prescribing, specialty drug prescribing, durable medical equipment, diagnostic testing, and surgical procedures.
7. Ensuring that Electronic Prior Authorization receipt of status checks and responses seamlessly integrate into EHR workflows
8. Ensuring a similarly seamless method for submitting appeals when an authorization has been rejected.
9. ONC and CMS should work together to address other contributors to the overall burden of prior authorization, so that a future state does not see us sending more and more low-value prior authorizations… electronically. Technical standards and capabilities are necessary, but not sufficient. This will mean reforms that reduce the overall volume of low-value prior authorization (for medications and tests where >90% are ultimately approved), making sure Electronic Prior Authorization can help implement gold-carding (where physicians who practice evidence-based medicine authorizations approved can be granted bypass status, like TSA pre-check), and making sure prior authorization systems don't pull patients off of medications on which they are stable for their chronic diseases or mental health conditions every time a new year starts or they change plans (protecting care continuity).
10. Having iterative real-world prior authorization system testing before any absolute mandate for use in practice, to ensure that the wide variety of systems that are needed for these end-to-end workflows are working together as envisioned.

We applaud the efforts of many to move forward these desperately needed standards and electronic capabilities. We believe they will only be as successful as their ability to help support patients receive the care they need and deserve in transparent and efficient manner, and their ability to support providers in helping care for their patients without undue administrative burden and loss of time. Technology and standards without a north star to guide the journey may lead us to get lost at sea.

Signed,

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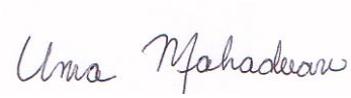

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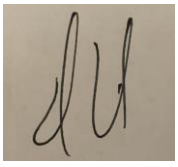

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