**Comments on Draft Strategy for Burden Reduction**

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EHRs and health IT were envisioned in “Crossing the Quality Chasm” as serving two primary purposes: (1) increasing the likelihood that healthcare delivery is knowledge-informed and thus consistently better and safer; and (2) EHR use would reverse the growing problem of administrative burden, most commonly expressed by physicians in the late 1990s as “I spend more time on paperwork than I do with patients. The IOM (now the NAM) further posited that leveraging EHRs to improve efficiency would create the time and space to improve quality – essentially meaning that care could be made better and safer by having clinicians work smarter, not more.

As we all know – that’s not how things worked out. By 2014, EHRs were seen as the primary source of physician dissatisfaction, and true or not, the complaint of the late 1990s morphed into, “I spend more time with my EHR than I do with my patients.” What happened? A perfect storm of documentation burden and regulatory burden – which in large measure contributed to poor EHR usability (EHR burden), further complicated by the fact that the EHR never even attempted to address the pre-existing condition of administrative burden.

While many unhappy physicians forget (or if they started practice with an EHR and after 1997 – never knew) documentation burden was not caused by the use of EHR checkboxes, templates, or the practice of “copy and paste.” Rather, EHR checkboxes, templates, and the need for “copy and paste” arose because of arcane regulations – the 1995 and 1997 Evaluation and Management Documentation Guidelines Documentation (DGs) that prescriptively defined the level (and thus potential payment) of a cognitive service, by the length and formatting of a clinical note.

At the time DG’s were introduced into American healthcare, most clinicians were using paper records. The response to the DGs for these physicians included both educational efforts and the creation of a hybrid note. These hybrid notes contained either handwritten or dictated narrative, plus a paper-based template which contained checkboxes – most often used to ensure compliance with the documentation guidelines for the HPI, ROS, and PE sections of a note. In fact, the first “pitch” and business case for the EHR to the physician outside of a computer science or research setting was in response to the DGs. Physicians could avoid cumbersome paper-templates and hybrid notes by having the DGs embedded into their EHR. And further, physicians could not only avoid fear of failing a coding audit; using embedded coding decision support with their EHR, they could learn how to consistently “right-code” their notes – and thus was born the first ROI for small-practice EHR purchase.

It did not take very long for this “solution” to be viewed as a problem. Physicians on paper records often created one outline–type clinical note to comply with billing requirements (the DGs), and then created a separate narrative note to send to other physicians. Physicians on EHRs (prior to VR technology becoming mature) often paid for their EHRs by using money that previously was spent on transcription services. These doctors believed that their now legible notes were good enough – and the EHR template-driven bloated note was the note used for compliance with billing AND to send to others. In fact, I believe the first instances of what we now refer to as “documentation burden” was identified first by EHR note readers as “cognitive burden” – as they would have to read thru many lines and pages of rote text to find a few kernels of useful information. But it was not long afterwards that note writers spoke about authorship documentation burden – or “click burden.”

Meaningful Use can be credited with helping to make the EHR mainstream, and mainstream in a very short period of time. This very real accomplishment unfortunately also resulted in the “collateral damage” of regulatory burden. This occurred because of a fundamental flaw in vision – the belief that the potential benefit of the EHR could be realized by clinicians in all specialties and scopes of practice using the EHR in the same way… which in turn led to use and certification requirements which Meaningful Use detractors labeled as “one-size-fits-none.”

It is my view that the incorporation of DGs and the creation of prescriptive regulations for Meaningful Use (and subsequent similar programs with other names, such as “Promoting Interoperability”) are the root causes of poor EHR usability or “EHR burden.” While EHR usability can improve on the margins by better software design; EHRs cannot realize their potential as highly usable and useful digital infrastructure without first acknowledging and addressing documentation and regulatory burden. Further, until EHRs fulfill one of their initial promises, their ability to reduce or even resolve administrative burden – the EHR will not be able to fulfill its other initial promise, that of being enabling infrastructure to help make care better, safer, and perhaps even more affordable.

HHS and ONC are thus on the right track, by understanding that the next phase in EHR maturation – where EHRs shift from being an additional source of burden to the enabling infrastructure of more effective and efficient care, will come first from burden reduction, and not from new regulations.

**Burden Reduction Goals**

Vision and goals are important, and this draft strategy is correct in calling out both documentation and regulatory burden. However, by failing to explicitly identify the reduction (or removal) of administrative burden – HHS and ONC are missing a fundamental point. What was the value of the public and private investment in EHRs and other health IT if the result is to bring us back to the less-burdened baseline of 1995 (prior to the first emergence of the DGs)? Our vision should include the hope that EHR use, by tackling administrative burden, can make care better. In fact, as much as I appreciate the primary label and focus on “burden reduction” I would suggest that HHS and ONC consider that “burden reduction” is in service of the larger goal of “value improvement.” We all want EHRs to shift from negative to positive (not from negative to neutral) because we want their use to lead to better care for people… and not just less annoyance to doctors.

**Issues and Challenges**

While containing many accurate and important points, I believe this list is not quite right...

1. In general EHRs are not being consistently used for their intended purpose – which is to make care better, safer, more affordable, and more accessible
2. While payment policy is evolving away from volume and towards sustainable business cases that also reward thoughtful use and re-use of information - efficient and effective use of EHRs in support of better care is currently hindered by burdens and distractions of:
	1. Arcane clinical documentation guidelines for payment purposes;
	2. Regulatory burden associated with the former Meaningful Use program and the current Medicare QPP;
	3. Reporting burden for Medicare QPP and other value-based payment programs; and
	4. The failure of EHRs to reduce / resolve pre-existing administrative burdens
3. I view EHR usability as a second order problem - as one could say that where the primary drivers of EHR adoption were satisfying billing and Meaningful Use requirements - EHRs were designed with that in mind. Until these distractions / burdens are addressed - it is not possible for vendors to redesign EHRs to optimize care.

**Health IT Usability and User Experience**

These are all important to address, but again I view the poor implementation of summary visualizations as collateral damage from overly specified regulations – particularly those that forced the EHR to look and function the same regardless of specialty and/or scope of practice. It is worth noting that prior to the Meaningful Use program, non-certified specialty specific EHRs were popular and well-reviewed by many physicians… as these EHRs optimized technology for workflows common to a particular specialty.

Consider this example of regulation poisoning function. Prior to Meaningful Use, my health system created an actual visit summary – typically ½ - 2 pages. And while it was customized by specialty, it focused on ALWAYS delivering to the patient: instructions, next visit, referrals and testing the patient was sent for, and changes to current meds (e.g., start taking this, or stop taking that…) and who to contact for more info or questions. All of you are aware of the sad next chapter, where the visit summary was defined such that it no longer had anything to do with the visit you just had; and there was nothing about it that could be considered a summary.

Another way to think about EHR usability is not in thinking about form design or use of color, but rather in how the technology supports complex workflow, such that what is not or rarely done now is consistently done in the future. What this means is that we move beyond the obvious small gains of digitizing paper and look at what EHR end-users now reasonably expect from their EHR, based in large part on their experience with other technology.

Here’s an example… Paper records typically had sections for notes, labs, imaging reports, flowsheets, correspondence, etc. A common workflow for doctors using paper records would be to:

* Receive a lab result;
* Have it placed in the right chart;
* Where other labs are easy to see, review the new lab result in context of prior ones;
* Where relevant, also review the problem and medication list (if new or changed treatments are called for);
* Inform the patient of the results and the change to treatment – by phone or letter.

Note that this workflow contained many conditional statements. In reality, because everything took so much time and effort – the most common ACTUAL workflow was for the doctor to view the single lab result, and either communicate or delegate communication of abnormals only. And as even that took time, a common alternate workflow, particularly when a new result suggested a change to existing medication – was to have patients make a follow-up appointment to discuss results.

Most EHRs digitized the paper record and provided marginal improvement in having information always findable. But that’s a benefit at the margin, and not what doctors have grown to expect when using technology. A better approach – which doctors would label as “useful and demonstrative of excellent usability” would be to have the EHR anticipate the multiple workflow steps listed above, and not require that the provider manually click thru each of these steps every time, but rather present them sequentially – thus making what this doctor might consider as an optimal workflow, something that was so easy to do that it was done consistently.

**EHR Reporting Burden**

Is EHR reporting burden a legitimate concern? Not necessarily. If the EHR is configured for Direct EHR reporting - and the configuration/mapping is done, accurate, and working as designed (which is a big if), the issue is not so much data access or reporting burden, but the disconnect between how a measure is rigidly constructed within a value set, and how a clinician assumes the measure is constructed. For example, it is now mid-January, and doctors and managers in my organization have gone from seeing many measure scores in a good to excellent range at the end of calendar 2018, to poor to mediocre scores now – as many Direct EHR measures reset themselves with the start of each calendar year. It is not reporting that is burdensome, but the fact that these measures as constructed – are not actionable for performance improvement. The burden then comes from what extra work is needed to make measurement meaningful and actionable.

One suggestion to improve functionality is to have Direct EHR measures produce reports that follow calendar logic, and a second set of reports that present a “rolling 365d” reporting period.

Another example of burden associated with Direct EHR measures is the prescriptive nature of value sets for medications and medication allergies. For example, aspirin 81mg may be entered as a structured medication on the medication list, but it may not satisfy the numerator for a particular measure, whereas aspirin 81mg chewable may satisfy the measure numerator.

**STRATEGIES AND RECOMMENDATIONS**

This section is clearly written and correctly expresses the complexity of administrative burden as something that must be considered within the larger healthcare delivery ecosystem – and not just as a provider function within the EHR. It should be noted that while HHS cannot directly script how non-governmental payers should act within the larger ecosystem of healthcare delivery; HHS can directly influence how Medicare (and to a lesser extent Medicaid) creates or reduces / eliminates administrative burden.

**Clinical Documentation**

While there will likely always be other reasons for something being documented aside from clinical, a thoughtful approach for HHS and ONC to take should include:

* As much as possible, cleave the amount and format of documentation from the definition of a service or service level (as has been started with the 2019 Medicare PFS).
* Think of documentation burden as extra work on the author and reader(s). The burden extends to more than time. It can also include loss of context, focus, and/or meaning.
* As much as possible – attempt to leverage what is in the EHR or other connected digital sources, such that the principle of “write once, use many times” can be applied.
* Understand that its not just documentation that can be burdensome; its also determining the content that needs to be documented, and for what purpose. This is most clearly seen within prior authorization.
	+ Example #1. The ideal / less burdened prior auth process is one that is based on transparency of accurate, understandable, and actionable information to both patient and prescriber PRIOR to or concurrent with ordering. In this way, the doctor and patient can share in decision making as to what reasonable alternative could be ordered – without ever starting a prior auth process. This approach would not only decrease unnecessary documentation; it provides an opportunity to modify treatment or testing after being informed by member-level cost and coverage information – thus potentially also reducing cost to the patient (copay) and overall cost.
	+ Example #2. Where it is known in advance that a patient may need prior authorization for a treatment or testing, and it is also known that the information needed is not currently in the doctor’s EHR – those questions can be sent to the patient in advance of the visit. Here’s an example. Let’s say a patient is on Drug Z for neuropathy, and it requires prior auth each year. If the payer changes the prior auth requirement and now includes something that the doctor doesn’t have access to - but the patient does, the frustration of attempting to complete a prior auth form by asking questions of the patient would no longer have to take valuable time away from the visit – it could all be done in advance.

Copy-Paste

I would encourage caution in thinking about, and added caution in attempting to regulate copy-paste. Copy-paste in general is a feature of IT, and when used appropriately, it’s perhaps the only time saver in using an EHR. Furthermore, its primary driver in EHRs were not physicians or laziness, but E&M Documentation Guidelines. Prior to the recent changes to the E&M Documentation Guidelines, clinicians had to fully document Review of Systems and Physical Exam findings. Are we really saying that reuse of standard medical phrases for normal or common abnormal findings is to be avoided – and that the value of the observation is enhanced by uniquely typing the same correct content – letter by letter?

Further, because in many EHRs there is currently no other way to record and pull forward longitudinal history – many doctors use copy-paste to create and carry-forward complex longitudinal problems. And even after the burden reduction effort of 2019, which states that a physician may refer to a prior note without copying relevant features – a doctor may chose to copy-paste that section of longitudinal history, as it serves as a memory aid for himself – and a valuable summary for the next provider of care.

**Health IT Usability**

IMO, usability should be considered in the broader context of what one is attempting to achieve with a health IT infrastructure. Thus, one could incorrectly consider health IT more “usable” because its simple and doesn’t burden the clinician with important details – such as cost implications, prior history information a new decision, etc. Health IT usability should be viewed from the perspective of the end-user – but additionally the lens should be “does the health IT make the desired safer / better process easier to do?” A doctor who doesn’t need to know about preventive and chronic care needs concurrent with the provision of acute care would find alerts about preventive and chronic care needs to be annoying. Conversely, a primary care doctor should find should these alerts not only useful – but the only way that modern primary care can be effectively and efficiently practiced.

Further, we must be open to CDS supporting not just today’s care models, but also what we not anticipate as likely specialty-specific care for the near future. For example - if care of the future needs to incorporate non-visit based interactions, chronic care management, assessment of risk and awareness of risk during and between encounters, team-based care, adherence to clinical guidelines, awareness of cost, etc. - then in some cases we are building on "work as imagined" and not work as is.

The “north star” for burden reduction should then not just be burden reduction – it must include value improvement. Burden can be reduced without doing anything useful for patients. I implemented and used an EMR in 1997. No reporting, no MU, no incentive dollars. Back then, physicians typically had a 3-12 month learning curve, and then were often more productive and efficient than when they were practicing with paper records. Is a return to EHR use of the 1990s what we should be striving for? IMO no. We would have decreased burden but done nothing to leverage health IT to make care better, safer, or more accessible.

The responsibility for improving EHR usability does not belong solely with vendors. Software engineers need to understand the workflow that needs improvement and build highly useful and usable systems around these new digital workflows. For example, a clinician would understand the value of having a screen view that provides for rich informational viewing and context – simultaneous with a place to document or order. Engineers would not. Usability needs to be engineered in the context of the totality of workflow – not just screen by screen.

IMO “click burden” is largely misunderstood. From a non-clinical perspective, all clicks might be thought of as bad. But of course, that’s not true… In the arena of word processing, most people appreciate that one or more extra clicks have been added to the “delete” document process, but not the “save” document process… as the implications of a mis-click when deleting a document are grave (and non-existent for saving a document).

Usability can also be thought of as enabling context. Here’s an example… It is not uncommon for patients to have multiple physicians taking care of different and sometimes the same problem. It is also not uncommon for questions to arise surrounding discontinuing a medication. Currently, the doctor fielding the question as to medication discontinuation might not be the original prescriber – and because medications within EHRs currently don’t contain a field for “who own’s this medication” – physicians might either not respond to this question, or punt it back to the patient with some non-advice such as “you should probably call all of your specialists to make sure everyone is ok with you stopping the medication.” From a “click-burden” perspective – this field may appear burdensome… and yet from a workflow perspective, having this added piece of meta-data may save many minutes of time, and perhaps even the patient’s life.

**EHR Reporting**

IMO it would be a mistake to create financial incentives for EHR reporting. As we learned from the Meaningful Use program, incentives sound better than they actually are. Incentives are typically coupled with prescriptive requirements, which could refocus physician effort from reporting to AND after the incentive period ends – I would expect to see financial penalties for failing to report. Here is what I would consider a better approach to incentivizing EHR reporting:

* Where possible have documentation reflect routine care delivery and avoid as much as possible parallel documentation.
* Create feedback reports within standardized reports such that there is direct value to the doctor (and patient) of having embedded performance measurement.
* Include within this same package an easy way to validate measurement. Having worked in this space for a number of years – I understand that when doctors don’t believe their quality scores are accurate – they are often right. I have also worked in this space long enough to know the power of having physicians engaged in scores they trust – rather than enraged by scores they don’t.

**Public Health Reporting**

Here is another area where flexibility and thoughtfulness can be very worthwhile. Here’s an example… In our health system we had PDMP information auto-queue and display when a patient’s record was opened. That was appreciated by our doctors and routinely used. However, because it was auto-queued – we had no way to measure that it was requested / viewed. We then essentially had to break this efficient auto-queue and insert a checkbox.

**A Proposal to Replace the Current Approach to Prior Authorization**

The ideal solution is not to digitize prior authorization, as the current construct has two flaws that should not be continued in a more usable approach. First, the current approach requires a misstep to trigger a response for further information. We have an opportunity to push the interaction earlier in decision making, and by doing so enable a more efficient process, and one that is driven by transparency and shared decision making. And secondly, because prior authorization is now so cumbersome, it is applied (thankfully) less than all the time.

Here are examples of a better process. At the time of ordering, real-time understandable and actionable member-level cost and coverage information informs the order not just of coverage and prior authorization requirements – but also informs (in the case of meds) of cost (or relative cost) and co-pays. At this point in time, the prescriber and patient together decide if the better course is to back out of the order and use something else – and this would apply to meds covered by prior authorization, or even a choice between two or more covered medications. The prescriber / clinician and patient could also see in situations if prior authorization may be needed, which information in the EHR system already exists, and what else may be needed to be documented *de novo*.

IMO, this approach is not just superior in the abstract; by applying advanced interoperability under a banner of transparency, shared decision-making, and joint stewardship of healthcare resources – the process is considerably less burdensome, and also leads to higher value decisions.

There is another increasingly common problem in the prior authorization ecosystem; prior authorizations that occur as an aftermath of what are essentially direct-to-consumer marketing. Here’s an example… A Medicare beneficiary is called by a DME company and told that she may be eligible for a no-cost back brace and/or mobility device. We have experienced instances where the beneficiary has told the sales person “ok,” or “no thanks” – and in either case the “sales pitch” is presented (often via fax labeled “Immediate Attention Needed”) as a patient-initiated request. These requests often come to primary care doctors, who do not have the deep subject expertise to determine if one type of brace or mobility device is better than another, or even if either is actually necessary. A typical response is to shred the request, believing it may be fraudulent. Yet the company will persist with an escalation approach that might send these “orders” for signature multiple times a day. At some point, a clinician may take the path of least resistance and sign one of these. And of course, as these are sales pitches, often what is requested is the most expensive option. The clinician then receives a prior auth request to explain why “he ordered” these devices. What follows is often a nightmare of back-and-forth, communications.

The solution to this problem is multifactorial – but in keeping with the subject of burden reduction, one piece of the solution is to present to the ordering clinician a similar response PRIOR to the order being placed – where understandable and actionable information is presented as to what is covered, and what is not and why. This would result in less burden of form completion for doctors, a source of truth that goes beyond sales pitches as to what is actually covered, and hopefully lower spending for Medicare.

**A Proposal to Reduce Administrative Burden for Federal Employees**

There are administrative burdens other than prior authorization. Such burdens include communications such as sick slips and FMLA forms. ONC could begin the creation of an administrative burden reduction task force / committee – that could catalogue administrative burdens associated with federal agencies and standardize them in content and format – such that they are embedded into certified EHRs.

**Should Order Entry be Standardized?**

Probably, but IMO it would be a mistake to aim for standardization prematurely, or in such a way that would inhibit further innovation. For example, current CPOE is often no better than digitized paper-based ordering; it for the most part does not incorporate anticipatory decision support and order sets (bundles). For example, one could imagine an order set for a well-controlled diabetic with early renal dysfunction. This order set could set out a schedule of expected testing for a set period of time – which of course would allow for fuzzy logic (e.g., A1C at 6 months +/- 1 month) and change in order frequency based on results.

Another example of why order entry should not be standardized prematurely is that involving the question of smart order catalog. CPOE and eRx have resolved the problem of illegible ordering and transcription of orders from system to system – but have added perhaps even more serious problems of drop-down list errors, and errors from overly granular choices that the ordering clinician cannot resolve.

**Should Results Display be Standardized?**

Probably, but not until there is a better appreciation of the value of differing displays based on specialty AND not in such a way that future innovation is hindered. Again, recall the example of electronic results display doing nothing more than digitally displaying what is available now on paper. Such an approach adds minimal value. However, thinking of display coupled with other pieces of information (in addition to the one result in question), and having that either be programmed by specialty, or self-learned via machine-learning – that is IMO what should be strived for.

**Is Interoperability an Endpoint, or Infrastructure in Support of Better Healthcare?**

IMO, interoperability must be thought of as supportive infrastructure. When it is framed as an endpoint, the definition of success becomes circular (e.g., “we need more interoperability as there isn’t much now; we are successful because we have more interoperability.” If we instead look at interoperability as supportive infrastructure, we can then look at more tangible outcomes – such as “did interoperability improve ordering and diagnosis, reduce duplicative testing, etc. Did the clinician find that the information provided / made accessible was on balance helpful, or overwhelming / confusing?

Increased interoperability does not necessarily lead to less work and burden. For example, as an internist information is rarely useful or usable in a vacuum; history and context are key. For me, atomic interoperability of results not ordered by me would likely lead to confusion, increased work, and perhaps misdiagnosis… whereas molecular interoperability might be an ideal mix of new information plus context.

**Does the New Approach to Promoting Interoperability (within MIPS) Reduce Burden?**

I don’t believe so. For the most part, the burden associated with MU (or ACI or PI) was not from reporting – but from understanding requirements, and where normal workflow was not consistent, changing workflow. IMO the approach to ACI/PI using a base score and with multiple options to achieve performance points was flexible enough for most specialties. If it were possible, an even better approach would be to have attestations of use (similar to the Improvement Activities category with MIPS). Here’s why… What is currently being scored assumes that something done more means something is better. Are you really comfortable saying that ePrescribing 90% of the time is better than 80% of the time? I am not. I am concerned that the burden of Meaningful Use will return REGARDLESS of the number of measures reported on, as long as functional measures and measurement require clinicians to think about using the EHR to satisfy a use measure – rather than using the EHR to improve care. That is unfortunately the case for physicians such as myself, who are trying to spend most (if not all) of their time on EHR optimization approaches that improve care. It does not serve patients for me to have to talk to neurosurgeons about ePrescribing if it doesn’t fit their practice and workflow.

**What Should / Could Be Measured that Isn’t in EHRs and other Health IT?**

I think this is the wrong approach. There is always something one could measure – but why? IMO our goal should be to think of the EHR as supportive infrastructure (similar to interoperability), and not an endpoint in itself. As you are aware, we risk diverting attention to specific EHR functions when we measure them for purposes of determining performance. Our direction at this point in EHR development should be to have clinicians use EHRs appropriately in the service of better patient care. We don’t want to return to the metaphorical equivalent of having doctors look at their feet while walking.