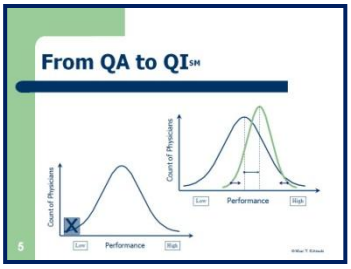
QA to QI LLC: A Patient Safety Organization

Evidence-Based Tools for Healthcare Improvement



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Comments Submitted via:
http://www.regulations.gov/#!submitComment;D=CMS_FRDOC_0001-1345

Attention: CMS-9954-P c/o Nidhi Singh Shah

Re: Section 1311(h) proposed rules, pages 170-175

I am qualified to comment on these proposes rules. I am a physician with more than 25 years of healthcare management and consulting experience. I currently operate an AHRQ-listed PSO. I also provide PSO services authorized by the State of Connecticut. I have done 3 national studies of clinical peer review practice and published 8 articles related to quality and safety since 2009. My most recent work is: A Longitudinal Study of Clinical Peer Review's Impact on Quality and Safety in U.S. Hospitals. Journal of Healthcare Management 2013;58(5):369-384.

ACA Section 1311(h) is very brief. It contains 3 distinct provisions: 1) hospital PSO reporting 2) hospital comprehensive discharge planning 3) mechanisms applicable to other healthcare providers for improving quality. These provisions have nothing in common. I believe that they require 3 distinct regulatory mechanisms. I will address them in reverse order.

I agree with the proposed rule regarding "other healthcare providers." This is clearly an area that requires further research by HHS and others.

I also agree with the proposal to use Medicare Conditions of Participation to satisfy the discharge planning requirement. This relieves QHPs of the burden of having to make independent assessments, relieves hospitals of the burden of having to submit to multiple assessments and reserves time to make a proper assessment of what constitutes effective discharge planning.

Under the CMS initiative to reduce readmissions, hospitals have in general put more attention on discharge planning. Plenty of clinical evidence on what really works is being generated from this effort, which can inform future regulatory policy decisions. Long term, the standards for discharge

planning under Medicare and ACA must remain aligned, so the proposed rule is also likely the best solution.

The remainder of my comments will address the issue of PSO reporting, because I strongly disagree with the proposed rule.

Page 170 of CMS-9954-P expresses concern that the existing AHRQ-listed PSOs may not have adequate capacity to contract with all hospitals having at least 50 beds that might wish to contract with a Qualified Health Plan, that there may be a significant burden for hospitals to enter a PSO contract, and that QHPs would have to invest in a tracking mechanism. None of these concerns are backed by data. I believe they are unfounded. An unwarranted delay in implementation of §1311(h)(1)(A)(i) will likely have a negative impact on progress in patient safety.

The language of §1311(h)(1)(A)(i) clearly expresses the intent of Congress that ACA should link to the Patient Safety and Quality Improvement Act of 2005. ACA has been the law of the land for nearly three years. Most affected hospitals have been aware, and all should have been aware, of the January 2015 deadline for PSO contracting. I and others have highlighted this in presentations and publications. See for example: Edwards MT. Engaging Physicians in Patient Safety through Self-Reporting of Adverse Events. Physician Executive. 2012;38(4):46-52. (Attached) Ordinarily in regulatory matters, there is no good excuse for procrastination, but this proposed rule has played to the hand of those who took a wait and see attitude.

Medicare Conditions of Participation are not a proper substitute for a PSO relationship. They do not address the creation of a Patient Safety Evaluation System (PSES); reporting of patient safety data in a standardized manner to facilitate large-scale data aggregation, analysis and feedback; or the provision of assistance to improve quality and safety. They are already the accepted standard in US hospitals. If they were sufficient to assure quality and safety, we wouldn't be facing such a huge gap between current practice and what is achievable. From this perspective, the proposed rule represents an abrogation of responsibility.

The regulatory problem can be easily solved by requiring the existence of a bonafide PSO contract by the January 1, 2015 deadline.

If this concept is accepted, HHS could eliminate ambiguity by specifying the procedure to be followed. To simplify matters for both QHPs and hospitals, I'd recommend that hospitals submit to the QHP an attestation of compliance signed by an authorized corporate officer indicating the name of the PSO together with the contract effective date and end date (or existence of an "evergreen" arrangement). In the unlikely event a PSO is de-listed, the rule should give affected hospitals some reasonable period of time (e.g., 3-4 months) to enter a new contract and provide an updated attestation.

This would be easy for QHPs to audit and track. The task is significantly less complex than that of maintaining network contracts and Business Associates Agreements with these same organizations. Assuming prompt publication of the final rule, even those hospitals which have procrastinated in

establishing a PSO relationship would still have ample time to comply. Hospitals routinely manage many hundreds of vendor contracts. Nothing special is required to enter into a contract with a PSO, even if additional time is required to establish the mechanisms and staff training to fully implement the relationship.

I am stumped to understand by what mechanism HHS believes a delay in implementation of §1311(h)(1)(A)(i) would generate increased PSO capacity. This piece of legislation gave promise of well-defined market demand. It has actually been instrumental in attracting entrants to the PSO industry and, thereby, increasing competition. There is no other market force that will drive a further increase in capacity. A delay in implementation could produce a devastating effect on existing PSOs by constraining the anticipated growth on which their business plans were built.

According to data from the February 2013 AHRQ-required PSO annual report, there were about 1660 general and specialty care hospitals with at least 50 beds under contract with a PSO. This represents nearly 40% of all US hospitals of that bed-size. The prevalence of PSO contracts increases dramatically with hospital size. As the following table shows, while slightly more than 20% of the smallest facilities have PSO contracts, nearly all the largest ones do.

General and Specialty Hospitals with PSO Contracts by Bed-size

	Feb 2012	% USA	Feb 2013	% USA	All USA	Gap
50 - 99	267	20%	295	22%	1,329	1,034
100 - 199	286	21%	316	24%	1,341	1,025
200 - 299	280	40%	339	48%	704	365
300 - 399	161	40%	215	53%	402	187
400 - 499	139	68%	187	91%	205	18
500 or more	228	72%	309	97%	318	9
Total ≥ 50	1,361	32%	1,661	39%	4,299	2,638

These data likely under-estimate the current total number of PSO contracts due to limitations in the methodology for data collection and the lack of information on growth since February 2013. AHRQ has made improvements which are expected to result in more reliable estimates in the 2014 annual report, which is due to be completed by the end of February.

Only about 300 hospitals entered into PSO contracts during 2012. The slow growth in 2012 most likely reflects market skepticism as to whether ACA would survive intact and whether HHS would enforce §1311(h)(1)(A)(i) as Congress intended. Therefore, this growth rate could be used to correct the above data for interval growth, but should not be used to estimate the capability for future expansion.

In fact, this small incremental growth grossly underestimates industry capacity. I estimate that at least 1,000 hospitals engaged in PSO contracts in 2009, the first year after AHRQ began implementation of the final rule. This was accomplished largely through the efforts of a small

number of organizations including ECRI, UHC and PSOs sponsored by hospital associations in California, Michigan, Missouri, Maryland, North Carolina and Florida. Since that time, other large companies have entered the market generating even greater capacity. Moreover, most PSOs have scalable infrastructure and could rapidly respond in aggregate to absorb doubled or tripled demand.

Correcting the above data from February 2013 for estimated interval market growth, roughly 2,300 hospitals would need to enter PSO contracts during 2014 if all of them intend to contract with a QHP under ACA. That's a big if. I doubt that all hospitals over 50 beds intend to have QHP contracts, but I found no data to estimate the proportion. Between the under-reporting to AHRQ, interval market growth and the likelihood that some hospitals will not contract with a QHP, the actual number of hospitals remaining to enter PSO contracts is no greater than 2,300 and is most probably substantially less.

It should be understood that PSOs come in different flavors. While many are oriented toward receiving and analyzing general safety incident reports, others are focused on a specific clinical domain such as anesthesia, radiation oncology, vascular surgery, pharmacy, etc. Still others may focus on a particular aspect of patient safety. My PSO, for example, provides services to help hospitals operationalize best practices in clinical peer review and event analysis. While these differences are relevant for hospitals seeking to establish a PSO relationship, they are irrelevant with respect to ACA. By design, all hospital-PSO relationships aim to improve the quality and safety of care. Therefore, all PSOs should be treated equally under the final rule for administration of §1311(h)(1)(A)(i).

PSOs are physically headquartered in only 29 of 50 states. Nevertheless, geographic location is not material to the task of providing PSO services and does not constrain access. PSO services are not intrinsically limited by state boundaries. Reporting of patient safety work product is preferentially done electronically, as is the majority of the feedback from PSO to providers.

You have asked for comments on what core aspects should be included in hospital patient safety programs. I fail to see how this could be a regulatory issue related to ACA. The law only asks for "utilization" of a PSES. Given the constraints of the Patient Safety Act and its Final Rule, there is no practical way to ask for more than the existence of a bonafide contract between the hospital and any PSO. The regulations do not require documentation of a PSES. Moreover, the mere fact of reporting of PSWP to a PSO is protected information and cannot be disclosed.

That said, the issue of what is included in a hospital patient safety program may be important for effectiveness. It may also be relevant from an accreditation perspective. Either way, it's a matter best left to the marketplace to resolve. By implementing §1311(h)(1)(A)(i) on schedule as intended, HHS will elevate the importance of PSO participation and hospitals will be stimulated to engage more intently on issues of safety and quality. That by itself does a lot to advance safety.

To my knowledge, Connecticut is the only state that has authorized PSOs independently of the federal statute. Since this might be put forth as a reason to create an exception under §1311(h)(2), I should provide some detail. The Connecticut statute (CGS Sec. 19a-127o) was enacted in 2004. It

is brief and has no associated administrative rules. Although the statute says, "Each hospital or outpatient surgical facility shall seek to work with one or more patient safety organizations as they become available," in practice the Department of Health has acted as though participation is mandatory for hospitals and ambulatory surgical centers. The statute defines and provides for the protection of state-PSWP. There is no provision for reporter protection or patient safety evaluation systems.

The complication arises that state PSWP can be entered as a copy into a federal PSES, but the reverse is not true. Federal PSWP cannot become state PSWP without violating disclosure rules. The Connecticut Hospital Association (CHA) had formed a federal PSO which serviced most state hospitals, but de-listed because of the problem managing this complexity.

It might be argued that, because Connecticut has its own insurance exchange, an exception to §1311(h)(1)(A)(i) should be made to allow substitution of contracts with CT-authorized PSOs. I believe this would be a mistake. Now that the federal PSO program is fully operational, the Connecticut statute has outlived its purpose. Patient safety data from CT hospitals is not required to follow the AHRQ-developed Common Formats, does not get aggregated on any larger scale than CHA, and does not contribute to AHRQ's national patient safety database. Good-faith reporters of quality and safety issues do not enjoy Patient Safety Act protection from reprisals. We know that standardization of process is the most basic principle for improving quality and safety. There are less than 30 acute care hospitals in Connecticut, all of which exceed 50 beds. Why should they operate to a different standard than the rest of the nation?

Thus, there is no longer a good rationale for Connecticut to follow a separate path with respect to PSOs. CHA could readily re-instate federal PSO operations or other PSOs could step in to provide services. The only potential complication is that, absent a compensatory regulatory change, hospitals might be compelled to have a relationship with both a state-authorized PSO and a federally-listed PSO. The state legislature could readily cooperate by repealing or modifying the statute or the Department of Health could back-off from requiring participation in a state-authorized PSO if a contract is in place with an AHRQ-listed PSO. Even in the worst case scenario, hospitals could still report PSWP to a federal PSO without wasted effort by entering state PSWP into their PSES as a copy.

If my comments have not been sufficient to convince HHS that PSO contracts should be required of all hospitals greater than 50 beds by January 1, 2015 in order to participate with a QHP, then the next best option would be adjust the size range as authorized under §1311(h)(3) to delay the requirement for the smallest facilities no more than 12 months. Based on the available evidence, a longer delay is unsupportable.

In this scenario, HHS would need a rationale for setting the cut-off level for compliance. According to AHA data, there are about 1,300 hospitals in the 50-99 bed range of which about 1,000 have yet to establish a PSO relationship. If that group was exempted, perhaps 1,300 others would need to enter a PSO contract during 2014. As I've shown, the industry has demonstrated its capacity to

absorb at least this much new business. Thus, the exempt range should in no case be higher than 50-99 beds. More realistically, it could be safely set to 50-74 beds and thereby exempt only 600-700 facilities. Such smaller hospitals are more likely than larger facilities to be located in areas without competition. In this way, the concern, however unjustified, that full implementation of the rule as intended would result in a shortage of eligible hospitals available for contracts could be mitigated without retarding progress in patient safety and with less risk of harm to the PSO industry.

Best Regards,

Marc T. Edwards, MD, MBA
President and CEO

Reference:

Affordable Care Act
§1311
(h) QUALITY IMPROVEMENT.—
(1) ENHANCING PATIENT SAFETY.—Beginning on January 1, 2015, a qualified health plan may contract with—
(A) a hospital with greater than 50 beds only if such hospital—
(i) utilizes a patient safety evaluation system as described in part C of title IX of the Public Health Service Act; and
(ii) implements a mechanism to ensure that each patient receives a comprehensive program for hospital discharge that includes patient-centered education and counseling, comprehensive discharge planning, and post discharge reinforcement by an appropriate health care professional; or
(B) a health care provider only if such provider implements such mechanisms to improve health care quality as the Secretary may by regulation require.
(2) EXCEPTIONS.—The Secretary may establish reasonable exceptions to the requirements described in paragraph (1).
(3) ADJUSTMENT.—The Secretary may by regulation adjust the number of beds described in paragraph (1)(A).