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July 22, 2008

Via Website
[http://www.regulations.gov/fdmspublic/component/main?main=DocumentDetail&o=09000064 8065a526] **Followed By Mail**

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1403-P
PO Box 8013
Baltimore, MD 21244-8013

Re: Proposed Incentive Payment and Shared Savings Program Regulations

To Whom It May Concern:

I am commenting on the proposed regulation discussion with respect to the proposed exception for incentive payment and shared savings program to be published at 42 CFR § 411.357(x). The bulk of my comments here pertain to the incentive payment aspects of these programs rather than the shared savings programs. I believe that the issues associated with these programs, while common in some respects, diverge significantly in others. The risk of underuse or reduced services in incentive payment programs is far less, since most current quality measures are oriented more toward underuse than overuse. If, as RAND researchers have demonstrated, the American Medicare population is receiving only fifty-five percent (55%) of what evidence says they should, improved quality performance would, of necessity, entail the delivery of additional services rather than the risk of reduction of services that pertain in shared savings programs.

I write from the perspective of an attorney who has worked more than thirty years on using legal vehicles like regulation to improve clinical quality. I served on the board of NCQA for twelve years and was chair for five. I maintain a website just on the business case for quality, primarily for physicians (www.uft-a.com). I have written extensively on hospital-physician collaboration for quality. (See www.gosfield.com/Publications) I am faculty for the Institute for Healthcare Improvement (IHI) program on "Engaging Physicians in a Shared Quality Agenda", and co-author of their white paper on that topic. I am chairman of the board and a founding Design Team member of PROMETHEUS Payment®, Inc., a tax-exempt corporation developing

a new provider payment model to pay for improved quality. (www.prometheuspayment.org) I am writing these comments from that perspective. No client has asked me to or is paying me for these comments. They reflect my own views from these multiple contexts.

I applaud the efforts to address permissible incentive payments for quality. Unfortunately, I believe the risks in gainsharing reflected in the proposed safeguards are overshadowing the positive potential available in incentive payments for quality where more flexibility should be allowed.

My primary concerns, as reflected in these comments, turn on the discussion that begins at 73 Federal Register 38553.

1. The restriction of remuneration to cash or cash equivalents only is too restrictive. Physicians who are performing at a high quality level might well value administrative burden reduction in their interactions with the hospital rather than cash. I would argue that administrative burden reduction, such as dedicated hospital staff to facilitate pre-admission testing, registration, or other similar in-kind benefits or amenities, should be permitted. Arguably these might not fall within the ambit of the Stark statute anyway, since they may not constitute remuneration; but the statement "non-monetary remuneration…to reward achievement of quality or cost saving goals would not be protected" could conceivably implicate administrative burden reduction as a non-monetary remuneration. Similarly, if the highest performing physicians were given PDAs with easy access to computerized physician order entry or other quality enhancing programs, why should that be problematic?

2. The emphasis on physicians "who actually participate," and "qualified physician organizations" being limited to organizations that consist exclusively of participating physicians is unduly restrictive and flies in the face of the well-recognized concept in quality improvement (as documented by the Institute of Medicine and others) that the best results are accomplished by a team of clinicians collaborating clinically. To the extent that the cardiologist refers at the optimal moment to the cardiac surgeon, the cardiologist has, indeed, contributed to effective results. Physicians who practice in multi-specialty groups ought not be penalized by virtue of a restrictive definition of "qualified physician organizations". (See comment at #11, too.)

3. The restriction of payment to payment on a "per capita" basis is limiting and unnecessary: It ought be explicitly permissible for hospitals to restrict participation in the incentive payment program to those physicians with sufficient experience with the institution and volumes of patients that their contribution to quality can actually be measured. Quality measurement principles have long focused on the problem of too small an "n" on which to measure. As a result, programs that are not offered to all members of the medical staff or even all physicians with clinical privileges relevant to the services that are the subject of the incentive payments ought be permitted. There should not be a single test. Where a hospital limits participation to those physicians on whom it has a track record, and uses an articulated threshold for participation in the program of both duration and volume, that should prevent the concern about physicians coming to the hospital to avail themselves of the incentive payment program. As long as the threshold to participate in terms of patients whose care is measure is articulated in

advance, and another standard of longitudinal affiliation, say at least six (6) months of data must be present to share in an incentive, should offer sufficient safeguards and flexibility. (But see comment #8 below as well.)

4. While the criterion of objective, independent medical evidence to support measures is a good one, the required limitation on how incentive payment programs might be structured is troublesome. While national measures themselves might form the basis for payments, the clinical processes that produce the actual score should be eligible for reward. For example, that door to balloon time is improved by physician response to call to attend a patient needing a procedure within fifteen (15) minutes of notification might well be a measure to be rewarded rather than the door to balloon time itself.

It is important in quality measurement to fix accountability at the locus of control. It is also important to reward the actions which actually produce appropriate results. Not all existing measures do either. (See Gosfield, "The Performance Measures Ball: Too Many Tunes, Too Many Dancers?," HEALTH LAW HANDBOOK, 2005 ed., [http://gosfield.com/PDF/Ch4Gosfield.pdf]) There is a fair degree of controversy within the quality community over whether individual metrics reflecting process measures, composite scores, or aggregate measures are the best way to achieve results. What if physician contribution to achievement of all six (6) of IHI's 100,000 Lives Campaign "planks" were rewarded? What if accomplishment of any one plank were rewarded? What if improvement in IHI composite measures were rewarded? The position taken in the preface to the regulations is too restrictive in an environment in which these issues are decidedly not settled and the opportunities to improve quality are so great.

As long as patients are not at risk of adverse outcomes and no physician is rewarded directly for the volume or value of referrals, the regulations should be unconcerned with how hospitals and physicians collaborate and clinically innovate to improve quality of care. As long as measures are stated in advance, reflect something objectively improvable, and payment is made on a basis stated in advance, that should be enough. Still further, to try to limit these approaches will only create fast obsolete regulations and will stifle innovation.

5. At page 38553 the statement is made "An incentive payment or shared savings program must be reviewed prior to implementation of the review." Reviewed by whom? Obviously the people involved in designing it have reviewed it. It appears that the statement is intended to require some estimate of impact on patient care. I do not understanding what it is seeking to accomplish in the context of incentive payment programs. If the phrase which follows that statement is intended to require that the impact of the measures be measured, that is inherent in the ability to pay the payment. If the metric actually measures improvement, is it intended that the program be evaluated to determine whether there is an adverse effect on quality? I find this provision illogical for incentive payments, although it is still unclear even for shared savings programs.

The requirement for independent medical reviews is an unduly expensive requirement for incentive payments. I can already foresee the legions of consultants charging vast fees to give

their imprimatur, itself of questionable value, to a program collaboratively developed between hospitals and physicians. Excluded are individuals "affiliated with the hospital operating the program". What extent of "affiliation" is problematic? Does this mean no physician on staff of one of the eight hospitals in the relevant system can perform the requisite reviews? Does this mean only new consultants may be brought in for this? While these comments reflect the approach that has been taken in the OIG Advisory Opinions issued so far with regard to the cardiac surgeon gainsharing programs, it is confusing and potentially inappropriate in the context of incentive payment programs.

That said, it is entirely legitimate to require that hospitals have an actual program which is written, quantifies, records, reports to the participating physicians and in a transparent manner to any patients who are interested, the outcomes and effect of the program. The issue of the independence of the review is not the real issue. Availability of data to the Secretary upon request is non-problematic.

6. The discussion of corrective action is confusing particularly in the incentive payment context. If patients are being harmed by the program, removal of the purportedly problematic measure or its modification would seem appropriate and logical. The sentence that begins "Also, although we do not want to encourage practice patterns…" appears to imply that once you are into the program you have to operate it for a year. That seems arbitrary. I have problems with programs being expected to operate for at least a year. If a metric proves to be inappropriate to capture physician performance, or not well articulated so that it cannot produce the relevant incentives, or inadequately communicated to produce the relevant response, it would seem appropriate to permit the program to be altered to accomplish the goal of improved quality. I leave no quibble with requiring that programs not be altered midstream merely to reward volume or value of referrals.

7. The implication at page 38554 that physicians choosing to be affiliated with a hospital with a culture sufficiently driven by quality as to be willing to pay physicians for their contribution to improved performance is a bad thing seems absurd. Competition among hospitals for the allegiance of physicians ought turn on quality; and if a hospital chooses to enhance its quality focus by compensating physicians for their contribution to a high quality culture this would be an appropriate reason for physicians to change their loyalty. That said, it would seem legitimate to require that the hospital have sufficient experience with the physician and that there be a sufficient number of patients on whose quality they can make judgments, so that physicians would not ping-pong to obtain incentive payments. Frankly, I do not think physicians function this way for the most part, but having a minimum tenure with the institution in order to participate in a program ought be sufficient to prevent improper responses to incentives. (See comments at #3 above).

8. For sharing to be only per capita and in pools of at least five (5) could be said to reward a team culture by paying otherwise competing physicians for their contributions to broader quality results, but that is something of a stretch. In some incentive payment settings these physicians may practice together; but in many settings they would be competitors. It is unclear what the goal is in the incentive payment context, although in shared savings it dilutes

the impact of any one physician's contribution to savings. The goal of a pool of five (5) is unclear.

Still further, depending on the specialty at issue, there may not be five (5) physicians of that specialty (such as infectious disease) on staff to create a five (5) physician pool. There is nothing inherently safer about rewarding five (5) physicians for their quality behavior rather than four (4). If they are paid per capita, as long as there are two (2) physicians, that should be enough. I could imagine reasonable incentive payment programs with differential payment to physicians based on how much they have contributed to quality scores, or the extent to which they adhere to clinical practice guidelines, or the extent to which they are valued as team players by the nurses. Still further, mandated per capita payments, combined with no thresholds for participation, will diffuse the incentive so it rewards physicians who have made no or little contribution to improved scores. Again, this is another place the shared savings and incentive payment programs regulations ought to diverge.

9. At page 38555, the exclusion from participation in a shared savings program of a physician who has a compensation relationship with a manufacturer of an item offered by the hospital is overkill. If the payments being made by the manufacturer to the participating physician are consistent with the Stark exceptions and the anti-kickback statute, that protection is sufficient so as to not have to exclude that physician from participation in shared savings, which all other similar physicians on staff would get.

10. Further on page 38555, the discussion of the safeguard to prevent altered referral patterns could have unintended consequences. To the extent that there are physicians with privileges at multiple hospitals, and in the course of implementing an incentive payment program, the environment improves at one of those hospitals so that the physicians shift their loyalty, this should be applauded and not prohibited. Competition among hospitals as to who has the safer, higher quality environment is something positive. This is a business case for quality, at long last. Competition on the basis of quality will create an ever-rising bar and improve the environment for the patients rather than disadvantage them. Again, where quality incentive payments are concerned, the risks are very different from shared savings programs.

The discussion of rebasing and limiting the duration of these programs has more validity in a shared savings program than it does in an incentive payment program. Obviously, to the extent that there are savings, as more savings occur, the pool of savings that are available for distribution goes down, and should go down. This is one of the main reasons that commentators like me have long said that gainsharing is a very short-sighted strategy for hospitals and physicians. Once the maximal savings have been achieved, what next? With regard to incentive payments, however, why should there be a sunset on an ever-rising bar of performance if it maintains performance at a high level? This is one of those significant areas where the protections for gainsharing versus pay for performance programs ought to diverge.

11. At 38556, the discussion of payments to multi-specialty physician organizations is too restrictive. It should be up to the physician organization to determine what they do with these monies. In fact, many physician organizations are specifically focused on the opportunity

to take these additional kinds of payments and use them to build infrastructure, whether to implement electronic health records, hire more staff, develop more educational materials, or otherwise engage in activities that will enhance quality. The notion that there should be any kind of obligatory pass through is absurd. Physicians in physician practices should be encouraged to collaborate as teams. That the money rests in the organization for distribution in the ways they see fit should be no concern of CMS.

12. At 38557, the emphasis on transparency is laudable; however, when and where the disclosure will take place, how the disclosure will occur, what form the disclosure will take, and how the disclosure will be monitored, are relatively opaque. Is it the hospital's obligation to make the disclosure or the participating physicians'? What is the penalty for an administrative failure in minor instances to comply? For the quality incentive programs, publication of their existence on a website and reference to that in a disclosure to a patient for a planned admission might work. What happens to patients admitted as emergencies? Again, the incentive payment programs that reward quality are a far different animal from shared savings programs that risk harm from reduced services.

13. At 38557, the discussion of safeguards against cherry picking is confusing. I gather the theory is that if a physician stops admitting more complex patients to the hospital as a response to some incentive, "the physician at issue must be terminated from participation in the arrangement." While the general notion that there is a structure to evaluate the impact of the program on patients would be useful, the conclusion that this means cherry-picking is going on seems extreme.

14. At 38858, the insistence that per capita is the only safe way to make these payments has been addressed above.

15. The notion that the hospital should maintain records to audit the impact of the program would seem to be inherent in the very idea of creating a quality incentive program. External audits are, again, an unnecessary administrative and financial burden for hospitals that are seeking to improve quality with the engagement of their physicians. Maintaining written records of programs, effect and payments, to be made available to the Secretary on request should be enough in the quality incentive payment context.

Conclusion

The risks to patients from shared savings versus incentive payment programs are very different. It appears that in an effort to protect against potentially harmful reduced services to patients, creative incentive payment programs would be restricted. Those programs should be subject to different rules where risk of harm is low.

I would be happy to discuss any of the observations I have made here. I do think that explicit protection beyond the relatively summary statement made at 72 Federal Register 61046 (September 5, 2007) allowing "compensation to reward physicians providing care in accordance

with quality measures" is an enormous improvement in the Medicare position vis-à-vis enhancement of quality.

Sincerely yours,

Alice G. Gosfield

(AGG/and)
cc: Lisa Ohrin (email only: lisa.ohrin@cms.hhs.gov)