



**BlueCross BlueShield
Association**

An Association of Independent
Blue Cross and Blue Shield Plans

By electronic mail

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Lou Felice
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Re: Medical Loss Ratios under Public Health Service Act Section 2718

Dear Mr. Felice:

The Blue Cross Blue Shield Association (BCBSA), which is comprised of the 39 independent Blue Cross and Blue Shield Plans (“Plans”) that provide health coverage to nearly 100 million Americans, appreciates the opportunity to provide additional comments as the National Association of Insurance Commissioners (NAIC) continues its work to provide recommendations to the Department of Health and Human Services (HHS) on Section 2718 of the Public Health Service Act (PHSA), dealing with medical loss ratios (MLRs). The NAIC’s Health Reform Solvency Impact (E) Subgroup has made great progress thus far in refining the Supplemental Health Care Exhibit discussion draft, and we appreciate the subgroup taking these additional points into consideration.

Health Quality Improvements - Recommendations for Supplemental Health Care Exhibit – Part 3

Health care delivery has changed tremendously over the years, with health plans playing a more prominent role in helping drive quality and safety improvements across the health system. Blue Cross and Blue Shield (BCBS) Plans are committed to improving quality and safety – for individual patients and for specified populations – by supporting a wide range of critical quality improvement activities needed to transform the delivery system. And Plans are continually innovating and testing new quality improvement (QI) activities. We are concerned that the definition of QI expenses proposed in the current draft of Part 3 instructions would support some but not all of these activities.

To encompass the full range of health plan activities designed to improve quality – for individuals *and* for specified populations – and to promote future innovation, we recommend three overarching revisions to Part 3:

1. **Explicitly allow health services for specified populations as QI expenses.**
2. **Design the QI definition to promote, not hinder, future innovation, by embedding the Institute of Medicine definition in the general definition, and by streamlining administrative complexity in other sections.**
3. **Incorporate references to Sections 1311 and 3011 of PPACA, to ensure that health plans' QI activities are consistent with current and future QI reporting requirements and state exchange QI strategies.**

What follows are recommended revisions to strengthen Part 3 that address each of our three "recommendation" categories. If these revisions are not made, health plans will face pressure to cutback on critical QI activities in order to live within the MLR administrative cap. Following each recommended revision is an example of a BCBS QI activity that supports the recommendation, but that might not be considered as falling within the current NAIC definition of quality activities.

We have attached to this comment letter a complete redline version of suggested language changes to Part 3.

1. EXPLICITLY ALLOW HEALTH SERVICES FOR SPECIFIED POPULATIONS AS QI EXPENSES

Issue: The Institute of Medicine (IOM) defined the quality of care as "the degree to which health services for individuals *and populations* [emphasis added] increase the likelihood of desired health outcomes and is consistent with current professional knowledge." This definition identifies both individuals (e.g., improvement in individual health status) and populations (e.g., reduced aggregate burden of illness and injury in a population) as proper targets for quality assurance efforts.

However, because the General Definition does not explicitly encompass health services to improve quality and safety for populations, and because the subsequent sections (Columns 1 through 4) in general address *only* health services for individuals, there is a high likelihood that vital activities to promote quality and safety for all patients, including health plan members – such as programs to reduce infection rates hospital-wide – would not be counted as QI expenses.

- **We recommend revising Part 3 to ensure that health services for populations, as recommended by the IOM, are embedded in the definition of QI expenses.**

Rationale: IOM called on leaders of organizations such as health plans to support accountability to individual patients while also assuming responsibility for accountability to public bodies and the community at large for the populations they serve. IOM noted that the application of epidemiological knowledge to large

populations and databases – applications well-suited to health plans with their vast data resources – will enable us to understand more and more about the dynamics of wellness and disease, which will redound to the benefit of individual patients. If the QI definition does not explicitly include health services for populations, the future of such programs is threatened.

The benefits of a population approach were expanded upon in a seminal 2007 article in the *Milbank Memorial Fund Quarterly*, “Using Population Segmentation to Provide Better Health Care for All: The “Bridges to Health” Model.” The model offers a way to think about developing programs for specified segments of the population that meet patients’ needs for coordinated, integrated care. When these programs are aggregated, they should improve the quality and efficiency of care for the entire population.

For certain types of patients who are extremely disabled or sick – such as those with significant disabilities, or heart or lung failure, or near death from cancer, or frail with dementia – **reliably improving their health requires fundamental changes in service delivery arrangements and the availability of important options. So sick and disabled are these populations that substantial re-engineering to ensure continuity of clinicians and to involve patients or their advocates in planning their care across multiple settings could prove to be among the highest priorities.**¹ Such QI activities focusing on specified populations will be more effective in improving health outcomes than QI activities focusing on one individual at a time.

For example, extremely sick patients hospitalized in Intensive Care Units are highly susceptible to central line bloodstream infections. Combating these infections requires the “substantial re-engineering” of hospital processes that is characteristic of a population-based approach to quality improvement. After years of research on effective steps in infection control, Peter Provonost of Johns Hopkins implemented this body of research into a multi-step checklist that translated the most effective known approaches into a series of hygienic precautions to follow when inserting, using, or removing a central line. Working with a state hospital association, a BCBS Plan was the first health plan to support testing Provonost’s ideas on a wider scale. This program benefited the Plan’s members as well as the broader hospital population.

Since then, BCBS Plans across the country have adopted the checklist approach to address another serious safety issue, surgical infection complications: the Blue Surgical Safety Checklist is the first in a series of resources created to educate and encourage providers to take proactive measures to help improve safety in the healthcare setting. The checklist, adopted from the World Health Organization Surgical Checklist, consists of 19 steps designed to improve communication and consistency of care within surgical teams. BCBS Plans have

¹ Joanne Lynn, Barry M. Straube, Karen M. Bell, Stephen F. Jencks, Robert T. Kambic. (2007). Using population segmentation to provide better health care for all: the “Bridges to Health” model.” *The Milbank Quarterly*, volume 85, number 2.

been sharing this Checklist with hospitals and physicians to encourage its use. This QI activity targeted on a specified population that included Plan members among a broader population has and will continue to save the lives of countless individual patients.

Explicitly including health services for populations also is necessary to achieve certain QI activities to improve health outcomes contained in PPACA and identified within the current NAIC definition, such as programs to reduce health disparities among specified populations and health plan accreditation programs. Identifying and addressing ethnic, cultural or racial disparities cannot be achieved through activities that improve care one patient at a time. Similarly, a core criterion for NCQA and URAC accreditation is to report aggregate information on outcomes for specified populations of patients, not to report outcomes for individual patients. Thus, adding “health services for specified populations” would clarify what the current General Definition already implies in certain areas.

Recommended Language:

General Definition:

Quality Improvement (QI) expenses are expenses, other than those billed or allocated by a provider for care delivery (i.e., clinical or claims costs), for health services for individuals or specified populations that are designed to...

Column 1 – Improve Health Outcomes

Expenses for the direct interaction of the insurer, providers and the enrollee (e.g., face-to-face, telephonic, web-based interactions or other means of communication ~~between and among patients and their providers~~) to improve health outcomes for the patient under the plan or coverage or to improve health outcomes for specified populations. This category can include costs for associated activities such as including:

Column 2 – Activities to Prevent Hospital Readmission

Expenses for implementing activities for individuals or for specified populations to prevent hospital readmissions, including:

Column 3 – Improve Patient Safety and Reduce Medical Errors

Expenses for implementing activities for individuals or for specified populations to improve patient safety and reduce medical errors ~~under the patient's plan or coverage through~~ including:

Column 4 – Wellness & Health Promotion Activities

Expenses for Programs for individuals or for specified populations that provide interactions ~~with the enrollee~~ (e.g., face-to-face, telephonic or web-based interactions or other forms of communication) that at a minimum include ~~between and among patients and their providers~~ that promoting:

Impact Examples:

Blue Cross Blue Shield Plans have supported a wide range of population-based quality improvement programs that have benefited their members as well as the community at large. Below are examples of these programs:

Example 1: BCBS plans recently launched a program to reduce childhood obesity and prevent future cases of diabetes. In consultation with the American Diabetes Association and the American Academy of Pediatrics (AAP) a nationally available “toolkit” was developed and distributed – a set of materials physicians can use to help parents and children become more motivated to adopt healthier lifestyles – to pediatricians and family practitioners in more than 1,600 physician practices. The materials assist physicians, children, and families in reducing childhood obesity.

Example 2: A radiology management program established by a BCBS Plan helps enrollees receive appropriate, quality diagnostic imaging exams and avoid excessive exposure to radiation (a quality issue of increasing concern, as evidenced by the House Energy and Commerce Subcommittee on Health’s recent hearing on risks of the use of radiation in medicine). The Plan provides the ordering physician with costs and quality information – based on evidence-based guidelines – about the available imaging providers within a specified geographic area.

Example 3: A joint initiative by a BCBS Plan, a state university and the Society of Hospital Medicine (SHM) to reduce preventable hospital readmissions by working with 15 physician organizations and 14 hospitals to implement the Society of Hospital Medicine’s Project BOOST (Better Outcomes for Older Adults through Safer Transitions) model. It involves training and mentoring to help physician organizations and hospitals develop, implement, and measure programs that reduce the incidence of patients being readmitted to the hospital within 30 days of their discharge. Participating physician groups and hospitals will share best practices and key lessons learned, leading to improvements in quality and safety for all in the specified population of patients admitted to the 14 participating hospitals.

Example 4: A population-based “National Surgical Quality Improvement Program” run by a BCBS Plan to improve quality and safety for surgical procedures. Through partnerships with 34 hospitals across its state, the Plan collects and shares data and best practices to improve quality and safety for surgical procedures: in one year, overall surgical site infections were reduced by 18%; overall surgical complications, by 37%. The American College of Surgeons recently gave an award to this program.

2. CRAFT THE QI DEFINITION TO PROMOTE, NOT HINDER, FUTURE INNOVATION

Issue: Several clauses in the general definition and in the subsequent columns would have a chilling effect on future innovations by erecting unnecessary barriers and unreasonably high standards. First and foremost, it is important to recognize that medicine is not black and white, it is a blend of art and science. That is why the IOM definition of quality speaks to increasing the “likelihood of desired health outcomes.” Second, the ability to innovate, to respond nimbly in a fast-changing medical environment, would be chilled by requiring the application of yet-to-be developed standards or unreasonably high standards of care. As the Joint Commission noted in its May 25, 2010 letter to the NAIC: “Many QI strategies are reasonable for insurers to engage in because of their likelihood to result in better care and services, but cannot yet meet a rigorous requirement that they are evidence-based. Until such time as there is more empirical evidence, insurers should not be discouraged from engaging in activities with a generally accepted, strong and close causal relationship between the QI expenditures and the anticipated population or enrollee outcome.”

We recommend revising Part 3 to promote flexibility in designing new approaches to improving quality, and to avoid chilling future innovations.

Rationale: To promote flexibility, the definition of QI should recognize the lack of “black and white” certainty in medicine by using the IOM language that QI programs be designed to “increase the likelihood” of desired health outcomes.

We also are concerned about a requirement that QI expenses be “based on standards developed independent of any particular health insurer” since such a criterion would put the cart before the horse. Standards are rarely developed and finalized until various approaches – often based on models developed by different medical specialty societies, accreditation bodies, or other national quality organizations – have been extensively tried and refined by health insurers and others in the real world.

Similarly, in the “Other” sections of each column, requiring prior approval by HHS would be another barrier to innovation because it would add an unnecessary and administratively costly layer of regulation that would slow down the rate of innovation. Advances in medicine move so fast, and differences across markets are so vast, that health plans need the flexibility to innovate quickly and to tailor programs to the unique needs of the local community. Adding layers of review that need prospective, empirical evidence on performance would slow or end needed innovations.

Also in the “Other” sections of each column, requiring that there be a showing that costs improve the quality of healthcare is an overly strict criterion that would hinder innovation by precluding initiatives that have value but cannot yet meet a cost improvement criteria.

Recommended Language:

General Definition

Quality Improvement (QI) expenses are expenses, other than those billed or allocated by a provider for care delivery (i.e., clinical or claims costs), that are designed to increase the likelihood of desired health outcomes and that are grounded in evidence-based medicine, widely accepted best clinical practice, or criteria issued by recognized professional medical associations, accreditation bodies, government agencies, or other nationally recognized health care quality organizations. ~~They should not be designed solely to control or contain cost. improve health care quality for health plan enrollees and advance the delivery of patient-centered medical care..~~

[The text highlighted in yellow was moved from the section below up into the main body of the General Definition.]

~~QI Standards: QI expenses should be based on standards developed independent of any particular health insurer, and be grounded in evidence-based medicine, widely accepted best clinical practice, or criteria issued by recognized professional medical associations, accreditation bodies, or government agencies. They should not be designed solely or primarily to control or contain cost.~~

Column 1

~~—Other expenses for programs designed in ways that can be objectively measured and verified to increase the likelihood of desired health outcomes for individuals or specified populations that meet the General Definition of Quality Improvement as may be approved by the Secretary in her or his discretion, in consultation with the NAIC, upon an adequate showing that the costs improve the quality of healthcare as set out in the first paragraph above; the burden shall be on the proponent to show that the expenses for the program conform to the definitionmeet these criteria.~~

Column 2

~~Other expenses for programsas may be approved by the Secretary in her or his discretion, in consultation with the NAIC, upon an adequate showing that the ~~costs are~~ designed to prevent hospital readmissions for individuals or specified populations that meet the General Definition of Quality Improvement above. The burden shall be on the proponent to show that the expenses for the program conform to the definitionmeet these criteria.~~

Column 3

~~Other expenses for programs designed to as may be approved by the Secretary in her or his discretion, in consultation with the NAIC, upon an adequate showing that the ~~costs~~ improve patient safety or reduce medical errors for individuals or specified populations that meet the General Definition of Quality Improvement above. The burden shall be on the proponent to show that the expenses for the program conform to the definitionmeet these criteria.~~

Column 4

Other expenses for wellness and health promotion activities for individuals or specified populations that meet the General Definition of Quality Improvement above. The burden shall be on the proponent to show that the expenses for the programs conform to the definition.

Column 5

Other expenses for programs which support as may be approved by the Secretary in her or his discretion, in consultation with the NAIC, upon an adequate showing that the costs support the activities described in columns 1 through 4 or otherwise support monitoring, measuring, or reporting health care Quality Improvement. The burden shall be on the proponent to show that the expenses for the programs conform to the definition.~~meet these criteria.~~

Impact Examples:

In 2008, many BCBS Plans across the country began developing targeted programs with participating physicians to determine the best ways to implement the patient-centered medical home model at the practice level. Had the current general definition been in effect, none of these programs would have been possible because standards for the patient-centered medical home did not (and still do not for a comprehensive range of models) exist. A May 2010 *Health Affairs* article, in noting the “novelty, complexity, and variety of medical home interventions,” underscores the chilling effect that would follow from requiring QI expenses to be based on already-developed standards.

Similarly, the medical home is a good example of a QI activity that lacks sufficient empirical evidence to show that costs improve the quality of healthcare. As noted in the May 2010 article in *Health Affairs*, “Evidence from the medical home pilots is currently scant...” Because medical home demonstrations began only recently, little evidence of their impact on health outcomes is currently available.

3. INCORPORATE REFERENCES TO SECTIONS 1311 AND 3011 OF PPACA

Issue: The current General Definition notes that “Qualifying QI activities are primarily designed to achieve the following goals set out in Section 2717 of PPACA.” Section 2717 articulates the quality improvement activities that must be reported by health insurers and group health plans. However, two other sections of PPACA are equally important in setting out quality goals: Section 1311 lays out the elements of a quality improvement strategy that must be carried out by Qualified Health Plans in the new Health Benefit Exchanges; and Section 3011 calls for a National Strategy on QI that lays out the national priorities with the greatest potential for improving the health outcomes, efficiency, and patient-centeredness of health care for all populations.

We recommend revising the General Definition to incorporate Sections 1311 and 3011.

Rationale: The elements of a quality improvement strategy in 1311 are the same as the elements to be reported in 2717 (except for the addition of health disparities, which is included in the current General Definition – and is reason enough to incorporate reference to Section 1311). However, a quality improvement strategy will not be a static document.

First, the Secretary is required to develop guidelines for the quality improvement strategy, and if those guidelines call for activities that do not currently appear in Part 3, then Qualified Health Plans might not be able to define those mandated activities as QI expenses unless Section 1311 is explicitly referenced.

Second, the application of the guidelines are required to be reported periodically, which implies that the guidelines will be adjusted over time to reflect experience – again, Qualified Health Plans need the certainty that as the guidelines drive changes in their QI activities, that the Plans will be able to define these activities as QI expenses.

Section 3011 directs the Secretary, as part of developing a National Strategy for QI, to identify national priorities that have the greatest potential for improving the health outcomes, efficiency, and patient-centeredness of health care for all populations, and to identify areas in the delivery of health care services that have the potential for rapid improvement in the quality and efficiency of patient care. The Strategic Plan must include “Strategies to align public and private payers with regard to quality and patient safety efforts.” Therefore, to ensure consistency and alignment with the National Strategy, it is essential that the evolving priority areas be defined as QI expenses.

Recommended Language:

General Definition

Improving Health Care Quality Expenses – General Definition:

Quality Improvement (QI) expenses are expenses. . .Qualifying QI activities are primarily designed to achieve the following goals set out in Sections 2717, 1311 and 3011 of PPACA; improvement must be capable of being objectively measured and produce results and achievements that can be verified to:

- Improve health outcomes including increasing the likelihood of desired outcomes compared to a baseline and reducing health disparities among specified populations;
- Prevent hospital readmissions;
- Improve patient safety and reduce medical errors, lower infection and mortality rates; or
- Increase wellness and promote health activities; or

- Enhance the use of health care data to improve quality, efficiency, transparency, and outcomes;

Finally, we would like to reiterate the importance of maintaining a level playing field among different health plan models for the quality improvement definition in the MLR standards. If any particular activity is ultimately excluded as an expense for health care quality improvement, then uniformly it should not be counted as a medical expense, including for group and staff model HMOs that may currently report certain quality-improving activities (such as disease and case management and health risk assessments) as medical expenses. Uniform treatment will create a level playing field on which consumers will be able to make informed, apples-to-apples comparisons among their health care choices. This uniformity is important to the quality provisions as well as the non-quality section of the Exhibit as discussed below.

Comments on Parts 1 and 2

In addition to the above recommendations for the Part 3 instructions, we would like to emphasize several key issues raised in our May 24 comment letter that refer to other sections of the Exhibit and that continue to merit careful consideration.

1. We have noted the importance of consumers having meaningful comparisons among all health plans, including the ability to easily compare medical and administrative spending among different health plans, and in particular, between group and staff model HMOs and other insurance models. To accomplish this Level playing field objective, all health plans should report costs uniformly. Today, staff and capitated model HMOs report many expenses as “clinical” that other plans include in the “administrative” category. A failure to address this discrepancy would mislead consumers because certain HMOs would appear to spend a relatively higher percentage on clinical services costs. As explained for quality improvement expense reporting, consumers should be able to compare plans on an apples-to-apples basis. Also, rebate implications should be taken into account. If there is a misplacement of expenses, consumers may be denied the potential for rebate for which they otherwise might have been eligible.
2. Reporting requirements should focus first on those elements specifically required by federal law, then phase in additional reporting not specified by PPACA at a later time. This would promote timely PPACA compliance, consistency with market segment rebating requirements, and achieve accurate and meaningful results for consumers and regulators.

Systems changes are needed to ensure the accurate, consistent and comparable information that the new federal requirements are intended to produce for regulators and consumers. To produce the proposed exhibits that go beyond federal requirements, such as reporting for “uninsured” and for Part 3, significant

systems upgrades are needed. Changes include systems enhancements to gather and warehouse data, to program algorithms (e.g., to allocate items such as investment income, federal income taxes and other expenses), and to develop processes to verify the results. The changes must be made within the new internal controls environment prescribed by the NAIC version of Sarbanes-Oxley (as known as the Annual Financial Reporting Model Regulation), which is vitally important but adds time and cost. A phased approach, such as permitting those elements not required by PPACA for year-end 2010 reporting not to take effect till year-end 2011 reporting, would best allow us to accomplish those goals while helping to manage administrative costs associated with these systems upgrades.

3. Line 1.5 – PPACA allows for the inclusion of all Federal Taxes and Federal Assessments. We recommend that the exclusion be deleted from the instructions for Line 1.5.

4. Line 1.8 - Fees for examinations by state departments are in addition to annual external auditor reviews but are required under state insurance laws. They are performed by state regulators, or their subcontractors, with the fees charged directly to the insurer even though the insurer has no control over the amount of the fees. We believe that statutory examination fees meet the definition of regulatory fees, and, therefore, should be included in the definition.

* * *

Thank you again for the opportunity to comment on the NAIC's Supplemental Health Care Exhibit discussion draft. We look forward to continuing to work with you on this issue.

Sincerely,

Joan Gardner
Executive Director, State Services

cc: Steve Ostlund, Chair, PPACA Actuarial Subgroup
Todd Sells, NAIC Staff
Brian Webb, NAIC Staff

Attachment