BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

1310 G Street, N.W.
Washington, DC 20005
www.BCBS.com

July 20, 2015

Office of Management and Budget (OMB)
Office of Information and Regulatory Affairs
Attention: CMS Desk Officer

Submitted via Email: *OIRA_submission@omb.eop.gov*

Re: New collection (Request for a new OMB control number); *Title of Information Collection:* Quality Improvement Strategy Implementation Plan and Progress Report (OMB control number: 0938–NEW)

Dear CMS Desk Officer:

The Blue Cross Blue Shield Association (BCBSA) appreciates the opportunity to submit comments on the Agency Information Request, "Quality Improvement Strategy (QIS) Implementation Plan and Progress Report" as issued in the *Federal Register* on June 19, 2015 (*80 FR 35362*).

BCBSA is a national federation of 36 independent, community-based, and locally operated Blue Cross and Blue Shield Plans ("Plans") that collectively provide healthcare coverage for more than 106 million – one in three – Americans. Plans offer coverage in every market and every zip code in the United States. Plans also partner with the government in Medicare, Medicaid, the Children's Health Insurance Program, and the Federal Employees Health Benefits Program.

CMS intends to have Qualified Health Plan (QHP) issuers complete a QIS Plan and Reporting Template ("the form") annually for initial certification and subsequent annual updates of progress in implementation of their quality improvement strategy. We appreciate how in response to our previous comments, CMS has removed and realigned elements to eliminate some redundancies and streamlined the QIS information collection tool, from two templates (a Plan Template and a Reporting Template) into one ("the form") to reduce issuer burden.

However, we believe the form still imposes an unnecessary administrative effort on issuers by requiring more information than is needed to evaluate issuers' quality improvement strategies for compliance with the requirements of Section 1311(g) of the Affordable Care Act. For example, we have strong concerns

about the necessity and utility of the following proposed data elements for the proper performance of the agency's functions, and recommend their removal for the following reasons:

- *Current Payment Model Description (Element 15)*—QHP issuers must collect information on the amount of FFS payments tied to quality or value or payments in an Alternative Payment Model tied to quality or value *across all product lines* [emphasis added], not for the QIS in particular. Therefore, this information is not relevant to evaluating issuers' quality improvement strategies for *compliance*.

- *Data Source (Element 16)*—QHP issuers must collect information on the data sources used for developing and monitoring their quality improvement strategies. However, given the potentially wide variation across issuers in the different data sources used to inform their strategies – some of which may be proprietary – and the lack of standardized definitions, it is unclear how this will help the agency evaluate the compliance and adequacy of QHP issuers' quality improvement efforts.

- *Goal(s), Measure(s), Performance Target(s) (Element 24)*—QHP issuers must collect information on clinical quality measures to monitory progress in meeting performance targets. We believe this detailed information is not necessary for CMS to comply with ACA requirements under section 1311(g) for guidelines to report on QIS implementation, and also duplicates QHP quality information already being collected through the Quality Rating System.

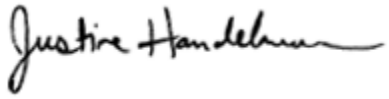
In addition, we have concerns regarding the feasibility of the QIS applying to the full enrollee population as well as the definition of market-based incentive being too narrow for addressing health and healthcare disparities:

- *Market-Based Incentive Types (Element 19)*—The current definition of market-based incentives offered by CMS is too narrow, and therefore could force issuers to implement programs and collect information that otherwise would not be necessary or may be duplicative of strategies issuers already have in place that address health and healthcare disparities. CMS should expand the incentives allowed for a QIS to include population-directed initiatives.

- *Targets all Plans Offered Through the Marketplace (Element 21)*—The QIS should not have to apply to the full enrollee population. A QHP issuer serving urban and rural areas, for example, may wish to encourage a payment structure in densely populated urban areas with a high degree of provider competition, but use a different approach in rural areas that does not involve payment structures. A one-size-fits-all approach would unfairly penalize and burden QHPs that operate in rural or underserved areas that lack the infrastructure for robust payer-provider interactions.

Our concerns are explained more fully in the detailed comments below. Thank you for your consideration of our comments. If you have questions, please contact Joel Slackman at joel.slackman@bcbsa.com or 202.626.8614.

Sincerely,



Justine Handelman
Vice President, Legislative and Regulatory Strategy

BCBSA DETAILED COMMENTS/RECOMMENDATIONS ON THE QUALITY IMPROVEMENT STRATEGY IMPLEMENTATION PLAN AND PROGRESS REPORT FORM

Part A. New or Continuing QIS Submission

Element 1: Type of QIS Submission

Issue. CMS has stated that QHP issuers participating in an Exchange for two or more consecutive years must implement and report on a quality improvement strategy (QIS). Those QHP issuers that began offering coverage in 2014 or 2015 would begin reporting a QIS for the 2017 coverage year; but those that began offering coverage in 2016 would begin reporting a QIS in 2018.

Recommendation. CMS should require all QHP issuers, not only QHP issuers who have been participating in an Exchange for two or more consecutive years, to submit a QIS implementation plan for the 2017 coverage year.

Rationale. Requiring only QHP issuers who have been participating in an exchange for two or more years will detract from the agency's ability to perform its compliance functions because it will deprive enrollees in newer QHPs of access to a QIS. Considering the broad parameters established by the ACA for a quality improvement strategy – a payment structure that provides increased reimbursement or other incentives for, among other things, improving health outcomes through quality reporting, care coordination, chronic disease management; preventing hospital readmissions; improving patient safety and reducing errors; and implementing wellness and health promotion – it does not seem necessary for a QHP issuer to wait two years to collect data to develop a QIS.

Put another way, it stands to reason that any QHP issuer will anticipate, regardless of the population enrolled, that there will be a need to improve health care outcomes through better care coordination, or reducing medical errors and adverse events, etc. Since QHP issuers will have the chance to change their quality strategy(ies) over time – as indicated in Element 28 – the year an issuer first sold QHPs on the Exchange should have no bearing on its ability to plan a quality program. Ensuring a level playing field, so that all QHP issuers play by the same rules from the outset, is necessary for the proper performance of the agency's functions.

Recommendation. CMS should clarify that if QIS information is eventually displayed publicly, it will display the same information for all QHPs (e.g., no QHP will be allowed to display information for three QISs when other QHPs have the one QIS).

Rationale. In the final rule of the 2016 Notice of Benefit and Payment Parameters, CMS stated that it "anticipates the display of a subset of this [QIS] information to promote transparency and will provide additional details through future guidance." If QIS information is ultimately displayed, it is important to

keep a level playing field across QHP issuers by showing information from *one* QIS form for each QHP, lest consumers gain the false impression that more QISs equals higher quality.

Part B. Issuer Information

Element 15: Current Payment Model Description

Issue. CMS is requiring QHP issuers to quantify the amount of FFS payments linked to quality or value or payments in an Alternative Payment Model tied to quality or value across all product lines (e.g., Medicare, Medicaid, commercial, Marketplace), not just applicable to the QIS described in this document. Although not part of the PRA, CMS has issued draft "Technical Guidance"[1] on filling out the form, which notes that reflecting all product lines "will help CMS gauge overall progress toward meeting value-based payment goals."

Recommendation. Delete this element from the form as it is outside of the scope of the Quality Improvement Strategy, as defined in 1311(c)(1)(E) of the Affordable Care Act.

Rationale. Earlier this year, HHS announced a value-base payment initiative, which includes measurable goals and a timeline to move the Medicare program, and the health care system at large, toward paying providers based on the quality, rather than the quantity of care they give patients. As noted in the Technical Guidance, CMS's requirement that QHP issuers quantify the amount of payments tied to quality and value is intended to help CMS gauge this initiative's progress. Such an information collection has no necessity nor utility for the proper performance of evaluating QIS compliance, and will impose an unnecessary cost and administrative burden on issuers.

Part C. Data Sources Used for Problem Identification and Monitoring Progress

Element 16: Data Sources

Issue. CMS is requiring QHP issuers to indicate the data sources used for identifying QHP enrollee population needs, and health and health care disparities, as well as for monitoring progress. These data sources include, but are not limited to: internal issuer enrollee data; medical records; claims files; surveys such as enrollee satisfaction surveys; plan data such as complaints, appeals, and customer service. This is a new data element that did not appear in the previous Plan or Reporting templates. Neither the "Supporting Statement for Information Collection: Quality Improvement Strategy Implementation Plan and Progress Report Form" nor the draft Technical Guidance explain the rationale for collecting this data element.

[1] "Quality Improvement Strategy: Technical Guidance and User Guide for the 2017 Coverage Year," (July 1, 2015)

Recommendation. Delete this element from the form, as its value for evaluating compliance with the QIS is unclear.

Rationale. As CMS indicates in the Technical Guidance, issuers may rely on a number of different data sources to inform their strategies. Keeping track of, collecting, and reporting what may be a considerable number of different data sources adds an administrative burden that appears to be neither necessary nor useful for the proper performance of the agency's functions.

Moreover, in the final rule of the 2016 Notice of Benefit and Payment Parameters, CMS stated that it "anticipates the display of a subset of this [QIS] information to promote transparency and will provide additional details through future guidance." Although CMS noted that "it does not intend the public display of payment structure information that is considered confidential or proprietary", including data sources opens up the possibility that proprietary information will be revealed. Even if CMS were to keep this information for internal purposes, it is important that it clarifies that its intention not to reveal confidential or proprietary information applies to data sources as well.

Part E. QIS Requirements

Element 19: Market-Based Incentive Types

Issue. The ACA defines a quality improvement strategy as "a payment structure that provides increased reimbursement or other incentives" for achieving a variety of quality improvement objectives. In the absence of statutory definitions of "other incentives," CMS has defined "provider market-based incentives" – which in addition to increased reimbursement include in-kind incentives; the draft Technical Guidance specifies in-kind incentives may include, but are not limited to, in-office nurses or physician extenders, staffing support to conduct care coordination, technical support for data collection – and "enrollee market-based incentives" – which may include premium credits, cost-sharing reductions/waivers, cash, or cash equivalents such as (according to the Technical Guidance) gift cards, gift certificates, diner's club points, provision of transportation, and memberships to gyms. This definition draws an arbitrary line that rules out other kinds of initiatives to improve quality that are also not directly related to financial incentives.

Recommendation. Expand the incentives allowed for a QIS to include population-directed initiatives such as grants to community organizations or direct outreach to populations in need.

Rationale. Expanding the incentives allowed would permit the following types of health plan programs to qualify as quality improvement strategies:

- Improving the Health of Disadvantaged Children. A health plan finds and funds local nonprofit

partners (e.g., 20 food banks) offering sustainable and measurable programs that reach children and their families in the areas of nutrition, physical activity, managing and preventing disease, and supporting safe environments. The health plan funds 18 mobile health vans that travel to underserved communities providing essential health screenings and immunizations to children and adults.

- Improving Vision Services for Underserved Communities. A health plan supports a mobile screening program that provides free vision services to children from 11 schools in remote, underserved communities.

- Improving Access to Underserved Areas through Telemedicine. A health plan provides multi-year grants to four community health organizations (three comprise providers) to expand the use of telemedicine in rural and underserved areas. One organization, a health system, is using its grant to extend teleconferencing and video-conferencing tools to its staff psychiatrists to care for about 1,200 patients of federally qualified health centers. Another, a clinic, will expand remote access to its bilingual counselors and healthcare providers through teleconferencing to about 650 patients. A third, a hospital, is partnering with a renowned psychiatric institute to provide initial evaluations and follow-up visits to 325 children and young adults with learning disabilities and behavioral health issues.

The form (Element 18) allows issuers to use strategies already in place, presumably to reduce administrative burdens. But defining incentives to include some programs that have little to no relationship to financial incentives (e.g., technical support to providers for data collection) and excluding programs that, for example, grant money to providers to help underserved communities is arbitrary. This will unnecessarily raise issuers' costs by forcing them to develop duplicative quality improvement strategies that would otherwise not be necessary.

Further, expanding the definition of incentives is necessary to solve an internal, logical inconsistency in the form (see element 23c below).

Element 21: Targets all Health Plans Offered Through the Marketplace

Issue 1. CMS is requiring all QHPs to have a Quality Improvement Strategy, applying to the total enrolled population of an issuer.

Recommendation. BCBSA recommends that HHS clarify that a QIS does not have to apply to the full enrollee population – a QHP issuer serving urban and rural areas, for example, may wish to make heavy use of a particular payment structure in densely populated urban areas with a high degree of provider competition, but use a different approach in rural areas that does not involve payment structures.

Rationale. QHP issuers need the flexibility to align payment structures and market incentives with the unique characteristics of their markets. A one-size-fits-all approach would unfairly penalize and burden QHPs that operate in rural or underserved areas that lack the infrastructure for robust payer-provider interactions.

Additionally, there appears to be inconsistency between the examples that CMS provides for market-based incentives and the reality of these programs being targeted to subsets of a population. For example, ACOs are cited as an example of a payment model (Alternative Payment Model built on a FFS architecture) that could be a viable QIS strategy. However, ACOs and bundled payment initiatives may be targeted to address the needs of a subset of a population. Any issuer using either of these payment models would likely need to also deploy multiple other QIS approaches in order to be broadly based and touch all members in the QHP. This would add significant cost and administrative burden to QHP issuers, and would tie their hands since they might have a rationale for targeting certain subsets.

Issue 2. QHP issuers are required to include a market-based incentive in all QIS activities.

Recommendation. BCBSA recommends that if a QHP serves an area where improvement strategies, that are not based on payment, are likely to be more cost-effective and successful than strategies that do not fit neatly into the market incentives orientation (e.g., rural, underserved, or provider shortage areas), that QHP should be excluded from the QIS requirements – unless HHS recognizes population-based, or community-oriented initiatives of the sort described above as QIS.

Rationale. If a QHP serves a market area such that payment structures are unlikely to yield significant improvements, that should be considered a type of QHP that is fundamentally different from QHPs serving areas with richer delivery infrastructures.

A real-life example of QHP issuers needing flexibility for targeting a subset of a population is in a state like Hawaii. BCBSHI looks at the need of its population by island, and has a different intervention for each island – not all of which are tied to a payment model. If the QHP issuer has a strategy to address healthcare disparities that does not include a payment model, we question why they should face eventual penalties if they are trying to improve the health of their population by other means?

Element 22: Rationale for QIS

Issue. The QIS Template requires issuers to enter a rationale for the QIS, including a narrative rationale that discusses how the QIS will address the needs of the current QHP enrollee population and a description of how the QIS will address health and health care disparities. The rationale should assess the needs of the QHP enrollee population and identify opportunities to reduce health disparities and gaps

related to access, quality, and health outcomes with an evidence-based approach.

Recommendation. BCBSA recommends that HHS provide further guidance on what is meant by "reducing health and health disparities" (including clarifying that activities may not necessarily include market-based incentives – see discussion under element 23), and give QHP issuers flexibility in focusing on those disparities of greatest importance to the markets and covered populations.

Rationale. It is well documented minority populations, on average, receive lower quality healthcare and suffer from higher rates of potentially avoidable complications compared to the general population. Quite often it is not possible to address healthcare disparities through incentives as defined in the current QIS design. The problem is systemic and requires partnering with network practitioners, public health agencies, local, state, and federal government agencies, and other stakeholders, to attempt to close gaps in care.

The lack of guidance is problematic because the National Quality Strategy sets out such a broad list of priorities to eliminate disparities in care, making it impossible to operationalize all factors in one program: the Strategy lists disparities as "including but not limited to disparities based on: 1) race; 2) color; 3) national origin; 4) gender; 5) age; 6) disability; 7) language; 8) health literacy; 9) sexual orientation and gender identity; 10) source of payment; 11) socioeconomic status; and 12) geography." Tracking disparities by race, ethnicity, and language (REL) is particularly challenging because sources of REL data are generally unavailable or impractical to obtain directly. Issuers do not comprehensively and systematically collect data on enrollees' primary language, level of English proficiency, or disability status.

Moreover, enrollment systems may not be configured to capture these fields without costly and time-consuming retrofitting. QHPs will face significant financial burden by having to capture and report information on market-based payments for health care disparities efforts, particularly if many of these initiatives may not have a financial incentive tied to them (e.g. QHPs may provide in-kind support through resources or toolkits to help providers address disparities). As a result, QHP issuers will end up spending significant funds to obtain data rather than the ultimate goal of improving the health of a population. Furthermore, the examples provided in the Technical Guidance and User Guide do not provide enough detail to help clarify which types of activities to address health and healthcare disparities would be acceptable.

Element 23: Activity(ies) that will Be Conducted to Implement the QIS (Must Pass)

Issue. The form requires that issuers describe how the activities relate to the selected market-based activities in element 19 and how the activities relate to health and health care disparities (if not selected as a topic area in element 20).

Recommendation. Clarify that market-based activities include a wider range of incentives, as recommended for element 19.

Rationale. The draft Technical Guidance recognizes that activities related to health and health care disparities do not necessarily include market-based incentives as currently defined. As an example of how to respond to element 23, the Technical Guidance lays out how an issuer who selects "preventing hospital readmissions" as its QIS topic area may respond. With reference to health and health care disparities, the example includes "developing communications materials for patients and providers in Spanish, Mandarin, and Creole that discuss the importance of follow-up care visits and compliance." This activity does not at all relate to the market-based activities in element 19.

Element 24: Goal(s), Measure(s), and Performance Target(s) to Monitor QIS Progress

Issue. QHP issuers must identify at least one (but not more than two) primary measures, and set performance targets for the measure(s). The draft Technical Guidance clarifies that issuers will not be penalized for failure to meet their performance targets *in the initial years* [emphasis added] – implying that issuers will be penalized after the initial years. Neither the PRA nor the Technical Guidance addresses the span of "initial years" (2 years, 3 years, etc.?).

Recommendation. BCBSA recommends that HHS not require clinical quality measures and performance targets to monitor strategy progress, as that is neither necessary nor useful for the agency to perform its functions.

Instead, QHP issuers should demonstrate their strategy progress through narratives and, at the option of the QHP issuers, structural and process metrics. For example, a QHP issuer may wish to use the measure proposed under Template Item 15; over time, what percentage of overall payments to network providers for the targeted population is associated with the QIS. Or, since the intent of capturing the percentage of payments linked to quality-related provider payments is to show an upward (increasing) movement – indicating the trend is putting more dollars toward quality in the evolution of payment reform – a better question may be, "Did the percentage paid to providers rewarding quality and value increase from the previous year percentage? Yes or No."

Rationale. In the "Supporting Statement for Information Collection," CMS simply refers to this recommendation and disregards it without addressing any of the concerns contained in our rationale. First and foremost, analyzing the progress of meeting performance targets would be needed to assess the *effectiveness* of a QIS, but evaluating effectiveness is called for neither in regulation nor in the ACA. Under 45 CFR 155.200, Exchanges must "evaluate quality improvement strategies". ACA sections 1311(g)(2) that the Secretary "develop guidelines concerning [the QIS], and 1311(g)(3) that the guidelines require "the periodic reporting to the applicable Exchange of the activities that a qualified health plan has

conducted to implement [a QIS]. Therefore, CMS does not need to collect information related to performance in meeting clinical quality performance measures to evaluate issuers' quality improvement strategies for compliance with the requirements of Section 1311(g) of the Affordable Care Act.

This is a distinction consistent with HHS's intention in FFMs to certify any health plan that meets certification standards as a QHP. Moreover, an evaluation of performance targets goes beyond the scope of the ACA §1311(c)(1), which requires exchanges to establish criteria for implementing a QIS, and 45 C.F.R. §156.200(b)(5), which requires that QHP issuers "implement and report [emphasis add] on a quality improvement strategy or strategies described in section 1311(c)(1)(E) of the Affordable Care Act consistent with the standards of section 1311(g) of the Affordable Care Act."

In addition, requiring QHP issuers to set and track performance targets:

- *Duplicates other quality reporting requirements*—under the separate Quality Rating System, QHP issuers will have to collect, validate, and submit data on 31 clinical quality measures and 12 survey-based composite measures. If QIS goals are consistent with some or all of these measures, then the QRS score is sufficient to indicate to exchanges and the QHP issuer whether its QIS is succeeding.

  If QHP issuers need to provide additional measures, an already heavy administrative burden will become even more onerous. As we commented to OMB in June 2014 regarding "Agency Information Collection Activities: Submission for OMB Review; Comment Request (Document Identifier: CMS – 10520)," we believe the estimates for collecting and reporting data for the QRS are significantly understated compared to Plan experience. For example, in its March 2014 Supporting Statement – Quality Standards, HHS estimated collecting and reporting quality measures per QHP plan would be $117,424. But based on feedback received from Blue Plans, estimates to collect and report quality measures for QRS range from $275,000 to over $800,000 per year. Estimates to collect and report data for the ESS range from $30,000 to $150,000, and estimates must include the vendor fees, which may account for roughly 80% of the expense. We do not believe the QIS should increase the burden for issuers and stakeholders to implement different and multiple program requirements.

- *Will have a chilling effect on innovation*—designing the QIS to measure the effectiveness of a QIS may have the unintended consequence of suppressing innovation and incentivizing some QHP issuers to go after the "low hanging fruit" to ensure that they appear successful in the Reporting Templates. For example, why would a QHP issuer launch an untried, innovative approach to structuring incentives – especially when tangible, positive results may take three or more years to emerge – when there is a risk that the exchange or CMS will judge the QHP issuer's QIS as a failure? Furthermore, if a QHP issuer needed to change a strategy after two years, and then

again two years later – how could penalties be fairly assessed if quality improvement is a moving target? If CMS focuses on structural and process measures instead (e.g. is the QHP issuer actively monitoring progress, making midcourse corrections as needed, and demonstrating a commitment to the spirit of the ACA), the QIS will be a force for good.

Recommendation. If CMS keeps the requirement to set performance targets, it should clarify the length of the "initial years" period so that issuers can determine the amount of time they have to tweak or redesign their strategies.

Rationale. Once QHP issuers begin implementing their QIS, they need time to assess what changes need to be made in order to maximize improvements and to obtain adequate data and results regarding the effectiveness of their strategies. Considering the time, costs, and administrative burden already associated with developing a new approach, it would be advantageous to issuers to have a better sense of when penalties may go into effect so they can focus more of their attention on innovation and implementation, and less on worrying about penalties for failure to make progress.

Moreover, it can be assumed that CMS seeks to encourage novel health care solutions, so additional guidance regarding expectations will reassure issuers that they will not be penalized for using their best practices and executing a design that may require modifications but has great potential, as opposed to a safer, more simplified strategy that issuers know they will be able to accomplish and will not result in penalties.

Recommendation. If CMS keeps the requirement to set performance targets, it should provide further clarification for Element 24c regarding how QHP issuers should calculate the baseline, especially if QHP issuers are reporting on a new product or changing population, or if the strategy itself is brand new.

Rationale. An example of why this is confusing is as follows: If QHP issuers are using 2015 as a baseline year, 2016 is mostly about design and development of the QIS. If it then reports progress in 2017 (looking back at progress in 2016), there should be little appreciable difference since the previous year was centered on the process of design and development of the QIS (with start date of 2017). Quality improvement takes time and may not happen in annual increments – so how useful will this information be to CMS in the initial years of the QIS?

Recommendation. CMS encourages the use of national benchmarks for QIS performance targets, but should clarify that QHP issuers that utilize regional benchmarks will not be penalized.

Rationale. The use of regional benchmarks is more relevant to the consumer for decision-making and comparison. This approach is consistent with the recent direction CMS has taken with the Medicare Shared Savings Program along with various statewide and regional initiatives. Significant regional

variation exists in health care, therefore we recommend benchmarks set at regional or market levels rather than at the national level.

Element 26: Risk Assessment

Issue. QIS issuers are required to list any known or anticipated barriers, along with proposed mitigation activities for each barrier identified.

Recommendation. BCBSA supports this element.

Rationale. As there will be a learning curve in the first several years of the Marketplaces for developing the QIS, we agree with this element and appreciate the recognition of barriers.

Part F. Progress Report Summary

Element 27: Addition of Health Plans to the Issuer's QIS

Issue. Because there are scant details at this time on the elements and criteria required in the Progress Report (Technical Guidance and User Guide references that additional details will be published in the fall of 2016), it is difficult to comment on the burden associated with completing this portion of the template.

Recommendation. Provide flexibility for QHP issuers in responses provided in this section.

Rationale. In general, it is difficult to comment on burden associated with elements of Progress Report section when issuers do not know what additional details on the elements and criteria will be required.

Element 28: QIS Modifications

Issue. The QIS asks issuers to indicate modifications made to their strategies and to provide a justification and description of the change identified.

Recommendation. Further clarify whether issuers may change goal(s) and performance target(s), or whether the goal(s) must remain the same while the target(s) may change.

Rationale. Additional clarification will be beneficial to QHP issuers and will help in understanding where flexibility is allowed and which elements of the QIS are meant to be more static.