

## **OMB Comments On Supporting Statement**

### **Comment 1**

B1 on page 1 says that this form will “ensure pertinent information is obtained by QIOs to effectively process these complaints.” During the conference call, CMS indicated that the main pieces of information QIOs need are information to identify “the right patient, the right provider, and the right time period.” For what percentage of complaints are these 3 pieces of information the only information QIOs need to review the complaint? For what percentage of complaints would QIOs need to further interview beneficiaries to get additional information? (rough estimates are fine)

#### **CMS Response**

Information to confirm the identity of the patient, the involved physician/provider, and the time period are required for ALL complaints (100%) and currently, the “percentage of complaint where QIOs would need to further interview beneficiaries to get additional information” is 100% as well based on the way the process is designed. CMS has proposed changes to the processing requirements that will reduce the need for the additional interviews with the beneficiaries in tandem with the newly standardized form. These changes will improve processing time frames while also simplifying the burden placed on beneficiaries. The current processing instructions dictate that the QIO’s initial discussion with a beneficiary (beneficiary representative) be used only to collect basic information from the beneficiary and to advise the beneficiary that a Nurse will call them back at a later time. The QIO’s Intake Assistant then forwards the case to a Nurse who calls the beneficiary back at a later time (1-2 days) to collect all remaining information, including the description of the complaint. The complaint form is then mailed out to the beneficiary at the conclusion of this second call.

In June, 2009, CMS distributed proposed changes to the QIOs for review and comment. The DRAFT processing instructions were revised based on comments and placed in formal clearance November 17, 2009. The KEY changes detailed in the DRAFT instructions are as follows: The initial/first phone call to the beneficiary will be used to collect ALL pertinent information from the beneficiary/beneficiary representative, including the name of the patient, the name of the physician/provider, the episode of care (time period), as well as a general description of the complaint. In addition, the complaint form will be mailed to the beneficiary immediately following this initial call. These changes will decrease the number of phone calls the beneficiary must participate in, eliminate the need for repeated call-backs should either party not be available, and ensure the beneficiary obtains the complaint form more expeditiously (thereby getting the beneficiary into the formal complaint process earlier and with less phone calls). Other changes have also been proposed that CMS believes will facilitate the QIOs’ processing of complaints, including a detailed accounting of all information (questions) needed from the beneficiary to be asked on the first call, and greater focus on the utilization of the QIOs’ health care expertise rather than the beneficiary’s perspective, e.g., the beneficiary representative complains that her mother died b/c of a Coumadin overdose, but the QIO actually determines the mother died b/c of an underdose of dilantin. In essence, rather than force the beneficiary (beneficiary representative) to

be a health care expert, we have changed the process to place the burden more clearly on the QIO.

## **Comment 2**

B3 on page 1: what percentage of benes are likely to submit this information electronically, and what percentage are likely to submit this information by postal mail?

### **CMS Response**

Currently, most complaints begin with a phone call to the QIO, with the complaint form mailed to the beneficiary and returned to the QIO through the U.S. postal service (99%) after the second phone call with the Nurse. Letters (or complaint forms) are rarely received by the QIOs (1%) without any prior QIO involvement. Beneficiaries are not given the option to electronically (email) submit complaints because of concerns regarding protected health information (PHI). The DRAFT instructions currently in formal clearance will allow beneficiaries to submit complaints electronically via email, but QIOs will be directed to caution (via a script read to the beneficiary) the beneficiaries about the potential ramifications of submitting their complaint electronically. As CMS continues to improve the beneficiary complaint process, we envision that beneficiaries will be able to directly input complaints via the web that will then be routed to the appropriate QIO. However, this is still being developed.

## **Comment 3**

B12 on page 3: Please delete the paragraph that begins “There is no wage rate associated with this form.” Please replace with a general statement like “The respondents are Medicare beneficiaries, most of whom are retired. Reliable wage rates or methods to estimate the value of their leisure time were not available at the time of this ICR submission.”

### **CMS Response**

The change has been made.

## **Comment 4**

B13 on page 3: Depending on the percentage of benes who are likely to submit this form by mail, the cost of postage would be a capital cost. Please provide an estimate (rough estimate is fine).

### **CMS Response**

While a stamp costs \$.44, the form is normally mailed to the beneficiary in response to a call with the QIO, and the QIO provides the beneficiary with a postage paid self-addressed stamped envelope. Thus, the cost would be relegated to the estimated 1% of beneficiaries who mail complaint forms/letters to the QIO. This would roughly amount to no more than \$20 based on current complaint volumes (3500 complaints per year). It is likely that additional costs will be associated with the implementation of the electronic version of the form available through CMS' webpage, but at this time, we have no estimated date upon which the availability of the electronic version will begin and thus, we have no way of estimating these costs .

## **Comment 5**

B14 on page 3: Please provide an estimate of the cost of collecting and processing these complaints. While we understand that this is included in the CMS contract with QIOs, we are looking for an estimate of what that cost is. (Rough estimates are fine). Please also include this in the ICRAS/ROCIS database.

**CMS Response**

The cost per beneficiary complaint is roughly \$2,800.

**Comment 6**

B15 on page 3: Please include a general statement, as discussed during the conference call, that explains that this new ICR actually represents a reduction in burden because this form will replace the cumbersome process that some QIOs currently use to initiate the complaint review process.

**CMS Response**

Language has been added to item 12 in the supporting statement.

**Comment 7**

B17 on page 3: While we would be comfortable granting an exemption for the paper forms, we think it would be reasonable and fairly inexpensive to provide the expiration date information on the electronic forms. Is CMS amenable to this?

**CMS Response**

Yes.

**OMB Comments on Instruction Sheet**

**Comment 8**

Neither the form nor the instructions seem to tell the bene where to send their form. Where is this information provided?

**CMS Response**

Most complaints originate as phone calls to the QIO, and the new form is being coupled with changes to the processing requirements for all QIOs. The draft instructions were placed in formal clearance November 17, 2009 and are written from the perspective that most complaints originate as phone calls to the QIO, with the QIO then forwarding the form to the beneficiary through the U.S. Postal Service. The instructions require that the QIOs include a return-addressed postage paid envelop for the beneficiary to use. This represents the vast majority of complaints. However, for those remaining instances where the form is provided to the beneficiary via email, the QIO will convey the address in the email to the beneficiary. Lastly, our expectation is that the form will ultimately be made available through CMS' webpage, and we have already discussed including information identifying the pertinent QIO as part of the webpage roll-out of the form through the web-based process.

**Comment 9**

Do most Medicare benes understand what a "HICN" or "Medicare number" is and where to find it? If not, is it worth providing a short descriptor like "The HICN can be found on your Medicare card or billing statements."

**CMS Response**

Based on our information, beneficiaries are familiar with this term; however, since most complaints originate through calls from the beneficiary to the QIO (99%), CMS will ensure that the instructions appropriately reflect the QIOs' responsibility to explain completion of the form as a standard part of the phone call.

## Comment 10

One commenter said that QIOs always need to request a bene's medical records in order to process a complaint and that this is all a QIO can do when reviewing complaints. If this is true, then it may be worth clarifying in the instruction to Line 9 that "The QIO **will** need to request your medical records related to the complaint," instead of "The QIO **may** need to request your medical records related to the complaint."

### CMS Response

This is not accurate. Currently, QIOs have the authority to review any information necessary to complete the review. Historically, most QIOs only review the medical record while other QIOs may review information maintained outside the Medical Record. The Draft instructions currently in formal clearance more clearly delineate the QIO's responsibility to consider all relevant "information," including information that may be found outside the medical record. In addition, the instructions provide the QIO with increased flexibility should the QIO determine that based on the nature of the complaint, the medical record is not necessary to render a decision on the complaint. CMS is ensuring that the focus of the review is physician review rather than medical record review.

## Comment 11

In the conference call and in response to the comments from Holly Muyskens, CMS clarified that this form is needed to initiate the complaint review process. In other words, it is the first – and not necessarily the final – step in the complaint review process, and that the QIO may follow up with further questions and interviews. However, the statement at the bottom of page 1 seems to imply that the QIO will always make a determination on the complaint on the basis of this form alone ("The QIO will send you a **decision** on your complaint within \_\_\_\_ days of getting the signed complaint form"). Please clarify. Would the following statement be more accurate? "The QIO will **confirm receipt of your complaint form** within \_\_\_\_ days **and follow up with you if additional information is needed to proceed with the complaint review.**"

### CMS Response

The emphasis placed on the form being the initiation of a beneficiary complaint review is in response to the statutory requirement that QIOs obtain a "written" complaint from the beneficiary before initiating its review, and the fact that every QIO varies the amount of information they determine the beneficiary must provide in writing before they can initiate the review. A number of QIOs require that the beneficiary document every single piece of information in writing before the QIO will initiate the complaint review. In essence, the initial phone calls with the beneficiary appear to be used for little more than determining where to mail the form. Other QIOs require significantly less information be provided in writing by the beneficiary before initiating the complaint review. These QIOs require the exact same information to complete the review, but most information is collected orally from the beneficiary during the initial phone calls. The variation in the length, form, and content of the forms the QIOs have independently developed evidences these two divergent approaches.

In the new manual currently in formal clearance, CMS' overall goal was to simplify the process for the beneficiary while at the same time ensuring that the QIOs obtain all information from the beneficiary necessary to complete the review. The instructions both increase the QIOs' emphasis on the phone conversation with the beneficiary by specifically listing the information to be collected orally and simultaneously decreases the information that must be submitted in writing via the new form, i.e., the minimum information necessary to meet the statutory requirement that the complaint be "written." In the revised process, the phone call occurs prior to the beneficiary submitting the form, and there should not be a need to engage the beneficiary in additional discussions after receipt of the complaint form, except in rare circumstances.

With regard to the content of the sentence referenced, the intent of the sentence is designed to provide the beneficiary with an anticipated completion date of the review, since again, by this time the QIO has collected all information needed to resolve the complaint and the new manual has identified strict time frames that will apply once the QIO has obtained all pertinent information. Thus, our goal is to convey a more rigid estimated completion date to the beneficiary. The completion of the review is separate and apart from the acknowledgement of receipt of the complaint.

## **OMB Comments on Form**

### **Comment 12**

Please include the standard "PRA blurb" on the form.

#### **CMS Response**

XXX-This has been included.

### **Comment 13**

Please change the race/ethnicity categories to conform with the OMB standards:

[http://www.whitehouse.gov/omb/inforeg\\_statpolicy/#dr](http://www.whitehouse.gov/omb/inforeg_statpolicy/#dr)

#### **CMS Response**

The form was developed using section 2.b from Appendix A (Data Formats-Combined Question) of the Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (Excerpt from *Federal Register*, October 30, 1997). Appendix A allows for both two and one question collection of race ethnicity. We request that OMB provide more specific guidance if changes are requested to this question.

### **Comment 14**

Given that the instruction sheet will accompany the form itself, is the "For your information" section really necessary to print on the form itself? Perhaps CMS could replace this section with questions that some of the commenters believed would be useful for CMS and/or the QIOs to collect (e.g. information about the authorized representative, information about competitive bidding, etc.).

#### **CMS Response**

The original intent of this section was to 1. ensure that Project Officers during onsite could determine the time frame for completing the reviews and 2. Emphasize key facts the QIO must convey to the bene, i.e., if the instruction sheet is separated from the actual form, the beneficiary

would at a minimum obtain this key information on the face of the form itself. That said, we have deleted this section so that beneficiaries have increased space to describe their complaint. Information regarding the authorized representative is already included above, and separate instructions for QIOs to follow related to issues surrounding the authorized representative will be captured in the manual instructions currently in formal clearance. In addition, the information about competitive bidding appears to be outside the scope of this complaint process, which focuses on the quality of the care provided.

## **OMB Comments On Public Comments**

### **Comment 15**

Please provide a response to all public comments received. We would be interested in responses to the following comments/questions in particular.

#### **CMS Response**

See attached.

### **Comment 16**

Holly Muyskens

- o Since CMS has apparently changed the “age” field to “date of birth,” it might be worth including this in the response to Ms. Muysken’s recommendation to ask for bene DOB rather than age.

#### **CMS Response**

This has been incorporated into the attached response.

- o “We use the bene’s address as part of the verification that we have identified the appropriate person”: if one of the goals of this form is to make it easier for the QIO to identify the “right bene,” and if the commenter’s organization relies heavily on the bene’s address to verify that they have identified the right bene, is it worthwhile to include this question on the form?

#### **CMS Response**

Our primary focus in changing the form was to make it easier for the beneficiary or his/her representative to complete the form and file a complaint. The changes were not focused on making it easier for the QIO to identify the “right beneficiary.” However, we recognize that identifying the right beneficiary is key, but the address is not a piece of the information that must be placed in writing on the form. Instead, it can be obtained orally from the caller during the initial phone call, particularly since the majority of complaints are initiated by the beneficiary. In fact, several QIOs already collect this information orally and have not experienced any difficulty in identifying the correct beneficiary. This makes sense given that the majority of complaints are initiated by beneficiaries, but even in those instances where the beneficiary does not initiate the complaint, the beneficiary representative is normally a relative (spouse, son, daughter) of the beneficiary and still has easy access to the address. We also considered other similar processes, such as credit card applications, where organizations obtain most of the pertinent information, including addresses orally from the caller. This is the approach the new manual instructions will take, and the QIO’s Intake representative will input all the information collected from the beneficiary or his/her representative into CMS Case Review Information System during the call. We believe that the QIO’s request that the beneficiary’s address be included on the form is

maintaining focus on the complaint process as a “paper” process rather than a process focusing on the beneficiary.

- o “We also recommend requesting the location of the incident. The name of the facility is an essential element when reviewing a complaint. It is necessary when ordering the medical record.” Is it necessary to have the name of the facility when ordering the medical record? If so, then is it worthwhile to include this question explicitly on the form, if one of the goals is to make it easier for the QIO to identify the “right provider”?

#### **CMS Response**

CMS has changed the instructions (Line 7) and the form to denote that information regarding the location (address) should be included in the description of the incident or concerns. We took this approach rather than having a separate field on the form regarding the location because while this information is needed to process the complaint, it is not necessary that it be provided in writing. In fact, several QIOs already collect this information orally and have not experienced any difficulty in identifying the location of the event so that medical records could be requested. Similar to the beneficiary’s address and other data some QIOs are requesting being added to the form, we believe that this piece of information can be obtained from the beneficiary or his/her representative during the initial phone call. In fact, it is specifically listed in the Draft manual instructions currently in clearance as an item the QIO must request during the initial phone call.

More importantly, the changes to the process requirements also make it clear that in certain situations, the QIO must not wait for the complaint form to be received before requesting the medical records. If during the initial call, the beneficiary or his/her representative conveys a serious or urgent quality issue, the QIO will be directed to immediately request medical records or other information needed to resolve the complaint rather than wait until after the complaint form is submitted. Focusing on the information collected during the initial call rather than the receipt of the form will enable the QIOs to effectively carry out these instructions. In these situations, even a short delay in requesting information could have serious ramifications to the beneficiary or other patients. Our primary focus in changing the form was to make it easier for the beneficiary or his/her representative to complete the form and file a complaint. We believe that this request is maintaining focus on the complaint process as a “paper” process rather than a process focusing on the beneficiary.

## **Comment 17**

Center for Regulatory Effectiveness

- o What is CMS’s assessment of the volume of complaints regarding competitive bidding?

#### **CMS Response**

We have not received any complaints regarding competitive bidding via the QIO program. The QIO program’s beneficiary complaint process is focused on the quality of care received, which is unrelated to competitive bidding or Medicare payment issues in general. As examples, quality of care complaints relate to care issues such as the administration of incorrect medication dosages, mistreatment of beneficiaries by physicians or hospital staff, amputations of the incorrect appendage, or care that was generally poor even though it was necessary.

- o What does CMS and/or the QIO do with the information? For example, CRE suggests that CMS report that data in summary form semi-annually and make it publicly available.

#### **CMS Response**

Each QIO is statutorily required to publish an annual report regarding the various review activities performed, including the number of beneficiary complaint reviews. CMS is currently making revisions to the Information Technology system to improve the capturing of data related to complaints, but again because the nature of these complaints relates to quality and not to competitive bidding or payment type issues, it will not account for this aspect.

- o In general, does CMS have a way of systematically tracking the volume of complaints received, stratified by dimensions like type of service, so that CMS can pinpoint where there might be systemic problems? What can the CRIS system do currently and what dimensions can it stratify by?

#### **CMS Response**

Information regarding the number of complaints is available from CRIS. Data related to the type of service is limited since the focus of the care is the quality and not the specific items and/or services provided. Currently, data can be stratified by provider ID (provider type), confirmed vs. non-confirmed concerns, category of concern, type of review (quality, utilization and/or DRG), and dates of service. CMS also is redesigning CRIS to facilitate data capturing and improve trending. While the system is not fully developed, we anticipate the new system providing more sophisticated analytics regarding physician/provider-setting, care issues, including "Never Events," health disparities, etc.

### **Comment 18**

#### **Health Care Excel**

- o Authorized Representative: "This causes concern about potential HIPAA violations should information be released to someone who has self-identified themselves as the bene's representative, however has not been identified by the bene." Please address this. How does CMS propose to ensure that individuals claiming to be the bene's representative are, in fact, their "authorized representatives"?

#### **CMS Response**

CMS has provided the QIOs with an approach to make these determinations, which will be included in the Draft instructions currently in formal clearance. The majority of complaints are initiated by the beneficiary. However, in those situations where the beneficiary is not the caller, the QIOs have been instructed to determine whether the individual has been identified as an authorized representative by considering the hierarchy of available evidence. First, the QIO must determine whether the individual has been deemed the beneficiary's legal representative through Court Decree and if so, the individual should be able to provide evidence of this. If a court decree has not been issued (which will be the case in most instances), then the QIO must be knowledgeable of its State laws regarding who can be an authorized representative. Each state is different. Some states have detailed requirements regarding such designations, and these requirements can also cover the obligations of physicians/providers to recognize them, whereas other states have little to no guidance. If the QIO determines that there is no state level guidance, the individual may have a Power of Attorney, and the QIO is instructed to obtain a copy of this



document. If the individual does not have a Power of Attorney or similarly named document, CMS has already developed and published a form, called the Appointment of Representative Form (OMB no. 0938-0950), which QIOs have been instructed to utilize in processing a beneficiary complaint.

## **Comment 19**

NMMRA – Andy Romero

- o “The QIO complaint process is currently limited to medical record review.” Is this true? If so, would it be prudent to focus the form on those elements required to gain access to the appropriate medical records?

### **CMS Response**

While the QIOs have historically focused on the medical record review, we have changed our manual instructions to move away from focusing on the medical record. Instead, the QIO’s focus will be on any information the physician deems necessary to render a valid decision on the complaint, particularly since the precise content of the “medical record” can vary. Thus, information relevant to the physician’s determination may be located outside the medical record. Given that the QIO regulations allow for the QIO to request and consider any “information,” we are working to ensure QIOs more consistently recognize their ability to obtain pertinent information.

## **Comment 20**

Lori Schieferdecker

- o We are particularly interested in responses to questions 4, 8, 9, and 10.

*Question 4: On the instruction sheet, #5 is regarding the beneficiary’s authorized representative. It is unclear as to what, if any, proof of authorization is required.*

### **CMS Response to Question 4**

CMS has provided the QIOs with an approach to make these determinations, which will be included in the Draft instructions currently in formal clearance. The majority of complaints are initiated by the beneficiary. However, in those situations where the beneficiary is not the caller, the QIOs have been instructed to determine whether the individual has been identified as an authorized representative by considering the hierarchy of available evidence. First, the QIO must determine whether the individual has been deemed the beneficiary’s legal representative through Court Decree and if so, the individual should be able to provide evidence of this. If a court decree has not been issued (which will be the case in most instances), then the QIO must be knowledgeable of its State laws regarding who can be an authorized representative. Each state is different. Some states have detailed requirements regarding such designations, and these requirements can also cover the obligations of physicians/providers to recognize them, whereas other states have little to no guidance. If the QIO determines that there is no state level guidance, the individual may have a Power of Attorney, and the QIO is instructed to obtain a copy of this document. If the individual does not have a Power of Attorney or similarly named document, CMS has already developed and published a form, called the Appointment of Representative Form (OMB no. 0938-0950), which QIOs have been instructed to utilize in processing a beneficiary complaint.

*Question 8: On the instruction sheet, #9 informs the complainant that processing of your complaint “may” require the requesting of pertinent medical records. It is unclear as to when and for what reasons medical records would not be required to process the review.*

#### **CMS Response to Question 8**

While the QIOs have historically focused on the medical record review, we have changed our manual instructions to move away from focusing on the medical record. Instead, the QIO’s focus will be on any information the physician deems necessary to render a valid decision on the complaint, since the precise content of the “medical record” can vary. Thus, information relevant to the physician’s determination may be located outside the medical record. Given that the QIO regulations allow for the QIO to request and consider any “information,” we are working to ensure QIOs more consistently recognize their ability to obtain pertinent information. Our goal is to eliminate instances where the QIO unnecessarily focuses on the medical record, e.g., a beneficiary representative calls the QIO to complaint that the provider is using cloth diapers on her mother rather than plastic diapers. The key information (the provider’s policy regarding the use of cloth versus plastic diapers) would not be addressed in the medical record.

*Question 9: On the instruction sheet, #10 states, “A decision on your complaint will be made within \_\_\_\_ days of receiving the signed complaint form.” It is unclear as to what decision is being made. Is it that the QIO has reviewed the complaint and deems that they have the authority to proceed with the review or is it the decision as to the final outcome of the complaint review? If it is the latter, this could range from 85-165 days and there is no way of knowing in advance an exact number of days to insert in the blank.*

#### **CMS Response to Question 9**

CMS has already provided the QIOs with revised instructions, which currently are in formal clearance, and these instructions make clear that at the point in time the QIO is forwarding the complaint form to the beneficiary for signature, the QIO has already determined that the complaint is within its purview, i.e., the determination has been made that the QIO has the authority to complete the review. Thus, the sentence “A decision on your complaint will be made within \_\_\_\_ days of receiving the signed complaint form” is specific to the final outcome of the complaint review, and not the QIO’s authority to review the complaint. The manual instructions make this clear. This aspect will be covered in training provided to the QIOs prior to the implementation of the standardized form.

*Question 10: On the Medicare Quality of Care Complaint Form, #5 asks for information about the beneficiary’s authorized representative. Again, it is unclear as to what, if any, proof of authorization is required. The complainant needs to know that up front.*

#### **CMS Response to Question 10**

CMS has provided the QIOs with an approach to make these determinations, which will be included in the Draft instructions currently in formal clearance. The majority of complaints are initiated by the beneficiary. However, in those situations where the beneficiary is not the caller, the QIOs have been instructed to determine whether the individual has been identified as an authorized representative by considering the hierarchy of available evidence. First, the QIO must determine whether the individual has been deemed the beneficiary’s legal representative through Court Decree and if so, the individual should be able to provide evidence of this. If a court decree has not been issued (which will be the case in most instances), then the QIO must be

knowledgeable of its State laws regarding who can be an authorized representative. Each state is different. Some states have detailed requirements regarding such designations, and these requirements can also cover the obligations of physicians/providers to recognize them, whereas other states have little to no guidance. If the QIO determines that there is no state level guidance, the individual may have a Power of Attorney, and the QIO is instructed to obtain a copy of this document. If the individual does not have a Power of Attorney or similarly named document, CMS has already developed and published a form, called the Appointment of Representative Form (OMB no. 0938-0950), which QIOs have been instructed to utilize in processing a beneficiary complaint.

## **Comment 21**

Sally Johnson – Arkansas Foundation for Medical Care

- o We are particularly interested in responses to Ms. Johnson’s questions regarding “step 4” and “step 8”

*Step 4 of the form asks for race/ethnicity. This is not necessary and will be verified in the medical record, if it is obtained for review. It takes up a good portion of the form that could be used for gathering helpful, necessary information about the concerns of the complainant.*

### **CMS Response to Step 4 Comment**

The new form attempts to obtain the pertinent race/ethnicity data directly from the beneficiary in a current acceptable format as delineated in OMB directives rather than rely on the manner in which the information is collected by the provider. With increased focus on health disparities and the need for improved data collection, we believe including this information on the form is necessary despite the space provided, particularly since the QIO will be able to obtain any and all pertinent information related to the complaint through discussions with the beneficiary and the form does not limit the ability of the beneficiary to convey additional information in writing.

*Step 8: the complainant needs to know, and it is not stated on the form, that if he/she chooses NOT to reveal his/her identity, he/she will receive only a generic response at the end of the process. (This is the requirement under the current review process.).*

### **CMS Response to Step 8 Comment**

This requirement will be changed with the implementation of the new form and the Draft manual instructions currently in formal clearance. CMS determined that a beneficiary’s decision that he/she does not want the provider or physician to know it was him/her that filed the complaint should not impact the ability of the beneficiary to receive the results of the review. The two aspects are unrelated, and many QIOs did not agree with the logic or understand how it came about. In addition, many QIOs have asserted that even in those situations where the beneficiary expresses a desire to remain anonymous in filing the complaint, the provider or physician is able to figure it out based on the nature of the information requested by the QIO. Thus, prohibiting these beneficiaries from obtaining the results of the QIOs review had no impact.

## **Comment 22**

Gateway Health Plan

- o We are particularly interested in responses to question 2.

*Will utilization of this form change the manner in which plans are required to handle quality of care complaints? Will plans be required to send this form along with grievance decisions that may include quality of care complaints.*

**CMS Response to Question 2**

No. While CMS has been engaged in discusses to identify ways to improve coordination between these entities, the two processes are separate, and the plan's obligation will be limited to apprising the enrollee of his/her right to file a complaint with the QIO in the same manner.