

The Centers for Medicare and Medicaid Services (CMS) received comments from one entity with respect to CMS-10287 (OMB#0938-New). This is the reconciliation of the comments.

**Comment:**

It is essential that the QIO receive complete and accurate information to process a complaint efficiently and to avoid confidentiality breaches that occur due to inaccurate or incomplete information. We have concerns that this form does not adequately request essential information and may be difficult for beneficiaries to use.

**Response:**

We believe that this form collects all of the necessary basic information to commence review of the case. Most beneficiary complaints originate with phone calls from the beneficiary to the QIO, and during these phone calls the QIO has the ability to ask the beneficiary for any information deemed necessary to process the complaint. The form is not intended to restrict the QIO's ability to ask for and receive information. Rather, it is intended to simplify the filing of a complaint for the beneficiary by reducing the amount of information that must be supplied on the form. The commenter's statement that the form "may be difficult for beneficiaries to use" is not sufficiently clear to provide a specific response. However, the development of the new Beneficiary Quality of Care Complaint form was developed in consideration of all complaint forms currently used by the QIOs. While the various forms may have different aspects that may be helpful, the goal was to establish a single form that best meets the needs of the beneficiary and the QIOs.

**Comment:**

We appreciate the effort to decrease paperwork by designing a one page complaint form, but the desire for decreased paperwork needs to be balanced by recognition of the QIO's need to obtain correct, accurate, clear and complete information. The information received on the complaint form provides the foundation of the complaint process. The beneficiary complaint process is highly confidential and an inaccurate, unclear or incomplete complaint form can lead to a breach in confidentiality, such as misidentification of the beneficiary or contacting the incorrect beneficiary or physician.

**Response:**

We believe that this form collects all of the basic information necessary to commence complaint review, but does not replace additional contact(s) between the QIO and complainant. In most instances, beneficiary complaints originate as phone calls to the QIO. During these calls, the QIO may request all information from the beneficiary that is necessary to commence processing of the complaint. QIOs should not commence processing a beneficiary complaint until accurate, clear and complete information is obtained. The form does not restrict the QIOs ability to obtain additional accurate, clear and complete information that is necessary to complete review of cases.

**Comment:**

Again, we appreciate the effort to decrease paperwork by designing a one page complaint form, but the desire for decreased paperwork needs to be balanced by recognition of the beneficiary's need for a complaint form that is easy to read and fill out. Many Medicare beneficiaries have impaired vision. Please consider providing this form in a larger font size and with larger fields for completion by hand.

**Response:**

**Thank you for your comment. The form will adhere to standard CMS form requirements and will be compliant with Section 508 standards.**

**Comment:**

Many times beneficiary complaints involve multiple settings, such as hospital, skilled nursing facility and home health. It would be helpful if the form provided the option of adding additional fields so that essential information could be provided about each setting in an organized manner.

**Response:**

**We are aware that QIO's may need additional information not collected on this form. The form was developed with the intent of simplifying the filing of a written complaint for the beneficiary by only requiring the beneficiary to include basic information on the form. Emphasis was placed on decreasing the amount of information QIOs request in writing prior to the initiation of a complaint review. The QIO may collect all necessary information to supplement this form during additional contact(s) with the beneficiary and enter it into the CMS-identified Information Technology System.**

**Comment:**

It would be advisable to pilot this form with a group of Medicare beneficiaries and a QIO (prior to mandating its widespread use) to see if the form is usable by the target population and also provides enough information for the QIO to process a complaint about the quality of health care that the beneficiary received.

**Response:**

**Thank you for the suggestion, and we will consider all available options prior to implementation of the form.**

**Comment:**

We recommend adding a comment notifying the beneficiary that ordering a medical record from a physician's office may imply that a complaint has been filed, even if the QIO does not overtly notify the physician of the complaint.

**Response:**

**Thank you for your comment. We will consider your comment, however, please note that conveying this information to the beneficiary is not restricted by its absence from the form.**

**Comment:**

Is there a reason why the form asks for the beneficiary's age and not date of birth? If the QIO has the beneficiary's date of birth, the beneficiary's information can be located in the Program Resource System (PRS) system, confirming the beneficiary's identity and Medicare coverage. Many times the HIC # is illegible, or a number is transposed, causing the QIO to be unable to verify Medicare coverage or leading to a misidentification of the correct beneficiary. There may be multiple beneficiaries of the same age and same name. Many times QIOs receive a complaint from a family member in which the beneficiary's name is misspelled. It is preferable to have the name, the HIC number, the beneficiary's address and the date of birth for accurate processing of complaints.

**Response:**

**The form was developed with the intent of simplifying the filing of a written complaint for the beneficiary by only requiring the beneficiary to include basic information on the form. Emphasis was placed on decreasing the amount of information QIOs request in writing prior to the initiation of a complaint review. The QIO is not restricted from obtaining the beneficiary's date of birth or other information necessary to process the complaint. The QIO may collect all necessary information that is not included on the form during the phone call(s) with the beneficiary and enter it into the CMS-identified Information Technology System.**

**Comment:**

It would be preferable to obtain the address and phone numbers of both the beneficiary and the representative in separate fields for clarity and to eliminate confusion when mailing letters or contacting a person by phone. We use the beneficiary's address as part of the verification that we have identified the appropriate person. If only the beneficiary representative's address is provided, we have less information to use to confirm the identity of the beneficiary. If separate fields are not provided for the address of the beneficiary and the representative, please add a check box designating whether the address and phone number fields on this form refer to the beneficiary or the beneficiary representative.

**Response:**

**The form was developed with the intent of simplifying the filing of a written complaint for the beneficiary by only requiring the beneficiary to include basic information on the form. Emphasis was placed on decreasing the amount of information QIOs request in writing prior to the initiation of a complaint review. The QIO is not restricted from obtaining the address and phone numbers of both the beneficiary and the beneficiary's representative by the absence of both fields on the form. QIOs may continue to request this information from the beneficiary and/or his or her representative, which can be input into the CMS designated Information Technology System.**

**Comment:**

We recommend also 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. It is preferable to have it in writing to decrease errors and allow a beneficiary to look it up at home, if necessary, when completing the form. It is also helpful if the beneficiary is able to provide the address of the facility. This can prevent confidentiality breaches resulting from confusion between facilities with similar names, facilities having multiple locations, or facilities with names that have recently changed.

The name, address and specialty of the health care practitioner is also helpful when trying to determine who provided the care. For example, if only the name of the physician is provided, this increases the risk that the QIO may contact the incorrect physician. Frequently, there is more than one physician in the community with the same name.

Consider asking, "What could the health care providers or practitioners have done differently that would have prevented your complaint?" the answer to this question often provides insight into the central issue and points a QIO toward quality improvement activities addressing the complaint. CFMC, in accordance with alternative dispute resolution process designed by the former Beneficiary Protection Program QIO Support Contractor (BPP QIOSC), has added this question to our intake forms, has found it very helpful and would propose that this information be collected at the time of intake for all complaints.

When complete and accurate information is provided on the complaint form, the complaint can be processed more efficiently and with less risk of confidentiality breach. In order to accomplish this objective without overburdening the beneficiary, we would suggest that a statement be added to the instructions such as, "Please provide as much specific information as possible when completing the complaint form, so that the QIO can process your complaint. If you do not know the answer to a question, feel free to leave that section blank."

**Response:**

**The form was developed with the intent of simplifying the filing of a written complaint for the beneficiary by only requiring the beneficiary to include basic information on the form. Emphasis was placed on decreasing the amount of information QIOs request in writing prior to the initiation of a complaint review. The QIO is not restricted from obtaining the name of the facility or from asking the beneficiary during phone conversations "What could the health care providers or practitioners have done differently that would have prevented your complaint" by the absence of these fields on the form. QIOs may continue to request this type of information, which can be input into the CMS designated Information Technology System.**

**With regard to your suggestion to add the statement, "Please provide as much specific information as possible when completing the complaint form, so that the QIO can process your complaint" this statement is general in terms of what "specific information" is being requested. In addition, the suggestion does not clearly articulate where this would be included on the form or where the beneficiary would include this general information.**

**However, QIOs have been provided specific information that must be requested from every beneficiary beyond the specific fields on the form.**

**Comment:**

If the complaint form asks for names of witnesses, we recommend that the instructions include information about what will be done with the names of witnesses. Will they be contacted and interviewed by the QIO? Will a formal statement be taken? Currently, the QIO has no direction as to what to do with this information.

**Response:**

**CMS has recently announced efforts to redesign the Beneficiary Complaint process and standardize QIO operations. QIOs have already been given the opportunity to comment on proposed instructions related to the QIOs processing of a beneficiary complaint through the use of this form, and CMS will QIOs have instructions which clearly convey their responsibilities associated with use of the new form and the processing of the beneficiary complaint reviews prior to implementation.**