CMS Manual System

Pub. 100-10 Medicare Quality Improvement Organizations

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 6 **Date: AUGUST 1, 2003**

CHAPTERS	REVISED SECTIONS	NEW SECTIONS	DELETED SECTIONS
10		Table of Contents	
10		10000 - 10090	
10 - Exhibit		Exhibit - 10-1 - 10-3	

NEW/REVISED MATERIAL - EFFECTIVE DATE: August 1, 2003

Throughout Chapter 10, all references to Health Care Financing Administration (HCFA) are changed to Centers for Medicare & Medicaid Services (CMS), all references to Peer Review Organization (PRO) are changed to Quality Improvement Organization (QIO), and all references to Payment Error Prevention Program (PEPP) are changed to Hospital Payment Monitoring Program (HPMP).

Section 10000 - Statutory and Regulatory Requirements adds information relating to the Health Insurance Portability and Accountability Act and the Privacy Rule, 42 CFR Part 160, 162, and 164.

Section 10010 - General Requirements informs QIOs that the HIPAA Privacy Rule does not alter their authority to receive information required to perform contract requirements. Editorial changes made to improve clarity. Revises paragraph C, QIO's Notification Requirement, to clarify when a QIO does not have to provide notice. Revises paragraph E, Individual's Access to Information about Himself or Herself, and paragraph F, Disclosure to a Beneficiary's Representative, to improve clarity.

Section 10030 - Confidential Information revises paragraph B, Disclosure of Confidential Information, and paragraph C, Information about Interns and Residents, to improve clarity.

Section 10050 - Disclosure of Confidential QIO Information to Officials and Agencies revises paragraph C, Disclosure to Consultants and Subcontractors, and paragraph F, Disclosure to Licensing, Certification, and Accreditation Bodies, to improve clarity.

Section 10070 - Disclosure of QIO Information for Research Purposes - Quality Review Study (QRS) Information clarifies the process for de-identification of data for release when requested by researchers, including the process for linking such data with CMS claims data.

Section 10080 - Disclosure of QIO Sanction Information makes technical correction to reflect regulatory language and updates regulatory references.

Section 10090 - Re-disclosure of QIO Information makes technical correction to reflect current regulatory language.

Workload and Costs: These instructions do not represent an increase in workloads or costs.

NOTE: Normally red, italic font identifies new material. However, because this release is a new manual, normal text font is used for the initial release.

Quality Improvement Organization Manual

Chapter 10 - Confidentiality and Disclosure

TABLE OF CONTENTS (Rev. 6, 08-01-03)

ACQUISITION, PROTECTION, AND DISCLOSURE OF QIO INFORMATION

10000 - Statutory and Regulatory Requirements

(Rev. 6, 08-01-03)

A. Part B of Title XI of the Social Security Act (the Act) -- This part contains several provisions that affect the confidentiality of your information.

- Sections 1154, 1156, and 1160 of the Act provide the statutory bases for the acquisition, protection, and disclosure of your information.

- Section 1160 of the Act also establishes the scope of your authority to disclose information for program purposes, including any required mandatory disclosures. It also addresses your responsibility to protect your information from unauthorized disclosure and provides penalties for unauthorized disclosure. Section 1160(a) specifies that you are not governed by the disclosure provisions contained in the Freedom of Information Act.

B. Regulations at 42 CFR Part 480 -- These regulations implement the above referenced provisions of the Act and describe your authority to disclose information and your responsibility to protect it from unauthorized disclosure.

C. Sections 1171 - 1179 of Part C of Title XI of the Act (Added by §§262 and 264 of the Health Insurance Portability and Accountability Act (HIPAA) (Public Law 104-191)) -- These sections require the Secretary to adopt standards to facilitate a national electronic health data system, including standards for certain administrative transactions, code sets, and health identifiers, and standards necessary to protect the privacy and security of health data. These standards apply to all health plans, including Medicare and the State Medicaid plans, as well as all health care providers that conduct electronic standard transactions.

D. Regulations at 45 CFR Parts 160, 162, and 164 -- These regulations (the Privacy Rule) implement the requirements of §§1171-1179 of the Act.

For purposes of the Privacy Rule, the Centers for Medicare & Medicaid Services (CMS) has made the following statements regarding submission of protected health information to Quality Improvement Organizations (QIOs):

- Medicare Quality Improvement Organizations (QIOs) perform certain review and other functions for the Centers for Medicare & Medicaid Services (CMS) under contracts with CMS. These functions are required under Part B of Title XI of the Social Security Act. Part B of Title XI also requires that covered entities disclose information on Medicare beneficiaries to QIOs so that QIOs can perform the requirements under their Medicare contracts. Covered entities that conduct certain electronic transactions and are subject to the Privacy Rule of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) generally cannot disclose protected health information on Medicare beneficiaries or other patients

without permission of the patients, unless the rule otherwise allows disclosure. If a covered entity's disclosure is required by law, the rule allows disclosure without the patient's permission under 45 CFR §164.512(a). Therefore, when a covered entity discloses to a QIO information on Medicare beneficiaries that the QIO needs in order to perform under its contract with CMS, patient permission is not required.

- Covered entities may also disclose protected health information about non-Medicare patients without their permission when the information involves the QIO's quality-related activities under its contract. Generally, when QIOs receive this information, they are functioning as health oversight agencies under §164.512(d). The HIPAA Privacy Rule defines a health oversight agency to include a Federal or other governmental agency or authority that is authorized by law to oversee the health care system (whether public or private), or government programs in which health information is necessary to determine eligibility or compliance with program standards (45 CFR §164.501). Oversight agencies also include a person or entity acting under a contract with the public agency. Part B of Title XI requires Medicare QIOs, as CMS' contractors, to conduct activities necessary for appropriate oversight of the health care system. Specifically, Medicare QIOs are health oversight agencies to the extent that they are acting under contract with Medicare to oversee the health care system in general or in compliance with quality standards under Medicare. This includes collecting and reviewing quality performance measures from hospitals regarding Medicare and non-Medicare patients, such as reports on surgical infection prevention, acute myocardial infarction, and influenza and pneumococcal immunization. When a QIO is acting as a health oversight agency, disclosures to them for health care oversight purposes are permissible without patient permission.

E. Section 1157 of the Act -- This section provides certain protections to those who disclose information to you. No person providing information to QIOs will be held, by reason of having provided such information, to have violated any criminal law or to be civilly liable under any State or Federal law, unless the information provided is unrelated to the performance of the contract of the QIO, or if the information was false or believed to be false.

The statutes and regulations cited above apply only to information collected, acquired, or generated by you as a result of your Medicare review activities. These provisions do not apply to non-Medicare information generated by your activities under another contract (e.g., Medicaid review, another contract with CMS, a contract with another Federal agency).

10010 - General Requirements

(Rev. 6, 08-01-03)

A. QIO Access to Information -- As specified in 42 CFR 480.111 through 480.113, you have access to medical records and other pertinent material that you need to carry out your statutory responsibilities. As specified in 42 CFR 480.114, your data collection is limited to the information needed to accomplish the purposes of Part B of title XI of the Act. The HIPAA Privacy Rule does not alter your authority to receive information that you require to perform the requirements of your Medicare contract. If medical/quality issues raised in the course of your review cannot be resolved by examining medical record information alone, request the additional information you need to make a determination. At its option, the facility may (but is not required to) provide you with internal documents such as incident reports. If the facility chooses not to submit the necessary information, make your determination with the information available.

B. Responsibility to Protect Information -- As specified in 42 CFR 480.115, implement reasonable security measures to ensure the integrity of your information and prevent unauthorized access.

- Confidentiality Plan -- Your written confidentiality plan must:
    - Address the regulatory requirements specified at 42 CFR 480.115;
    - Be sufficiently detailed to guide employees in day-to-day operations;
    - Include the security measures for protecting QIO electronic data and confidential information when it is offsite; and
    - Require prior approval by CMS for any use of data acquired, collected, or generated by you under your contract with CMS for purposes not included under your contract with CMS.
- Training of Personnel -- Instruct your officers and employees and health care institution employees participating in your review activities of their responsibility to maintain the confidentiality of information. Train all personnel involved in transporting confidential information to handle the material properly. Document all training in your security records.
- Transportation of Confidential Information -- All confidential information transported offsite must be handled properly. Store confidential information located offsite under lock and key. At a minimum, place material being transported by car in the car's locked trunk and never leave the car unattended during loading and unloading. When using public transportation, carry confidential material in a locked briefcase or suitcase.

Properly package confidential information mailed to or from offsite locations. Envelopes and other containers should consist of materials and be in sizes and shapes that facilitate mail handling and discourage breakage. Seal packages properly and use the type of tape that cannot be torn. Double-wrap packages to be mailed and identify on the inner

wrapping that the material is confidential, and indicate who is authorized to open the package.

At a minimum, send confidential information via first class mail. Use higher mailing levels when circumstances indicate the need for additional security.

C. QIO's Notification Requirement -- Prior to disclosing your information, comply with any applicable notification requirements in 42 CFR 480.104(a) and 480.105. Also, comply with the general notice requirements specified in 42 CFR 480.116 for the notice you must send to patients, practitioners, and institutions under review. Specific exceptions to the notice requirements are found in 42 CFR 480.106. QIOs are not required to provide notice of disclosure to the provider if the disclosure is made: (1) as part of an investigation of fraud or abuse by the Office of the Inspector General (OIG) or General Accounting Office (GAO), (2) as part of an investigation of fraud or abuse by any other Federal or State fraud or abuse agency and the investigative agency specifies in writing that the information is related to a potentially prosecutable criminal offense, or (3) as a QIO referral to OIG regarding probable fraud or abuse (Generally, OIG becomes involved only after other attempts, such as corrective action plans, have been tried (and failed) to correct a problem).

D. Verification and Amendment of QIO Information -- 42 CFR 480.134 requires you to verify the accuracy of your information and make any necessary corrections.

Individuals and facilities can request that you correct and amend pertinent information in your possession. At such request, advise the requesting individual/facility of your decision and any actions taken regarding the request. Make any corrections to your data that you determine are needed.

E. Individual's Access to Information About Himself or Herself

- Beneficiary -- Disclose information to the beneficiary or his/her representative within 30 days after you receive a written request as specified in 42 CFR 480.132. A beneficiary is entitled to have access to information pertaining to him or her, including psychiatric records and records concerning alcohol/drug abuse. However, if knowledge of the information would be harmful to the beneficiary, disclose the information to his/her representative rather than to the beneficiary. Determine whether direct disclosure would harm the beneficiary, in accordance with 42 CFR 132(a)(2).

Consistent with the disclosure authority at 42 CFR 480.132(a) and 480.132(b) (relating to requests that are connected with an initial denial determination), and as required by 42 CFR 478.24(a), upon request provide a beneficiary with an opportunity to examine the material you used as the basis for your initial denial determination. To comply with this requirement, provide the beneficiary with all pertinent material, not just the medical record. Include all practitioner-specific information concerning the services that the

beneficiary received. Disclose the practitioner-specific information with or without the consent of the practitioners identified (See 480.133(b)).

When a beneficiary's request for his/her medical record is not related to an appeal of your denial determination, as specified in 42 CFR 478.24(a), provide him/her with any applicable records in your possession, as required by 42 CFR 480.132(a). Before disclosing information under this authority, however, redact any material that explicitly or implicitly identifies practitioners, other patients, QIO reviewers, or QIO deliberations.

NOTE: Without prolonging the timeframes to release the records requested, you may encourage the beneficiary to seek the medical record from the appropriate hospital. If the beneficiary declines this advice, you are still bound to provide the records as specified above.

- Practitioners and Reviewers -- Disclose information to practitioners and your reviewers as specified in 42 CFR 480.133(a)(1). You may also disclose information on a particular practitioner or reviewer to a third party if the individual identified in the information consents to the disclosure. The disclosed information, however, cannot identify other individuals without their consent.

- Health Care Facilities -- Disclose information to health care facilities as specified in 42 CFR 480.133(a)(1). Facility-specific information is non-confidential unless the material is part of your deliberations or contains confidential information as defined in 42 CFR 480.101(b).

F. Disclosure To a Beneficiary's Representative -- Disclose information to the beneficiary's representative instead of directly to the beneficiary when required by 42 CFR 480.132, or when the beneficiary designates a representative. In seeking beneficiary information, a properly designated beneficiary representative may exercise the same rights and privileges as the beneficiary.

If the beneficiary is deceased, disclose the information to the first appropriate individual according to the following order:

- To the executor of the estate;

- To the administrator of the estate; or

- To an individual verified in writing to be the beneficiary's designated representative.

If the beneficiary is mentally, legally, or physically unable to designate a representative, disclose the information to a person whom you determine is responsible for the patient. You must first attempt to make that determination based on the medical record. If the medical record does not provide the necessary information, you may rely upon the

attending physician for the information. Disclose the information to the first appropriate individual according to the following order:

- The beneficiary's legal guardian;
- A relative or other person who receives social security or other governmental benefits on the beneficiary's behalf;
- A relative or other person who arranges for the beneficiary's treatment, or exercises other responsibility for his/her affairs;
- A representative of an agency or institution that did not furnish the services for which payment is claimed, but furnished other care, services, or assistance to the beneficiary; or
- A representative of the provider or of the nonparticipating hospital claiming payment for services it has furnished if the provider or nonparticipating hospital is unable to have the claim signed by one of the above-listed individuals or entities.

As specified in 42 CFR 424.37, when a party signs a claim, a request for a payment statement, or a review for an incapable beneficiary, he/she must also submit a brief statement that:

- Describes his/her relationship to the beneficiary; and
- Explains the circumstances that make it impractical for the beneficiary to sign the claim, statement, or request.

10020 - Non-confidential Information

(Rev. 6, 08-01-03)

A. Types of Non-confidential Information -- Non-confidential information generally includes any information that does not meet the definition of confidential information found in 42 CFR 480.101(b). It includes, but is not limited to, those items specified in 42 CFR 480.120(a).

Facility-specific information that does not contain your deliberations or confidential information (as defined by 42 CFR 480.101(b)) is non-confidential.

B. Disclosure of Non-confidential Information -- Disclose non-confidential information, upon request, as specified in 42 CFR 480.120. As provided by 42 CFR 480.121, you may also disclose non-confidential information on your own initiative.

Upon request, disclose material such as lists of your meetings and dates of their occurrence as long as there is no confidential information included in the material.

Disclose summaries of proceedings of your meetings if the material contains no confidential information.

10030 - Confidential Information

(Rev. 6, 08-01-03)

A. Definition of Confidential Information -- Confidential information is defined in 42 CFR 480.101(b).

B. Disclosure of Confidential Information -- Disclose confidential information only as authorized under 42 CFR 480.130 through 480.143. For all information gathered or developed as part of a Quality Review Study (QRS), follow the requirements at 42 CFR 480.140 (All Health Care Quality Improvement activities are defined as QRSs).

As specified in 42 CFR 480.135(a), disclose confidential information as necessary to fulfill your duties and functions under title XI of the Act. This includes any disclosures needed to properly complete the appeals process. As specified in 42 CFR 480.135(c), disclose confidential information to another QIO when the material is related to practitioners who are subject to review by the other QIO. This includes sanction information as well as any other pertinent information, excluding QRS information.

Disclose practitioner-specific information about potential and confirmed quality concerns to the involved practitioner and to the facility where the services were furnished (See §§7200-7250). Each facility should designate specific officials to receive your notices and other confidential disclosures.

C. Information About Interns and Residents -- Your disclosure of practitioner-specific information involving interns and residents is restricted in the same manner as other practitioner-specific information. Generally, you cannot disclose an intern's/resident's quality problems to program officials, attending physicians, or residency/intern program accrediting bodies without the consent of the affected individual. If the residency/intern program is operated by the involved hospital, however, quality review findings that you disclose to the hospital may be shared by the hospital with residency/intern program officials as internal communications, when appropriate.

D. Disclosure of Confidential Information To Elected Officials -- See §5010B.1.

10040 - Disclosure of QIO Deliberations

(Rev. 6, 08-01-03)

Regardless of any other provision, disclose your deliberations only as specified in 42 CFR 480.139(a).

10050 - Disclosure of Confidential QIO Information to Officials and Agencies

(Rev. 6, 08-01-03)

A. Disclosure to the Department of Health & Human Services (DHHS) -- Upon request, disclose confidential information to DHHS as specified in 42 CFR 480.130.

B. Disclosure for Purposes of Monitoring and Evaluation -- Upon request, disclose confidential information to CMS or any person, organization, or agency authorized by DHHS or Federal statute to monitor your performance as specified in 42 CFR 480.131. The information that you are required to disclose includes copies of medical records of Medicare beneficiaries that are maintained by health care facilities or health care practitioners.

C. Disclosure to Consultants and Subcontractors -- As specified in 42 CFR 480.135(b), disclose information to consultants and subcontractors when the individual/organization needs the information to provide you with specified services. Consultants and subcontractors should receive the same training and information about the subject as your employees.

D. Disclosure to Intermediaries and Carriers -- Disclose confidential information to intermediaries and carriers as specified in 42 CFR 480.136, which authorizes disclosure of information relevant to the intermediary's or carrier's responsibility for making proper payment determinations. This includes disclosures needed to coordinate medical review activities between you and the intermediary or carrier.

E. Disclosures to Federal and State Enforcement Agencies -- As specified in 42 CFR 480.137, disclose information related to investigations of fraud or abuse of the Medicare or Medicaid programs to Federal and State enforcement agencies.

F. Disclosure to Licensing, Certification, and Accreditation Bodies -- Disclose information to licensing, certification, and accreditation bodies as specified in 42 CFR 480.138(a)(1). A licensing, certification, or accreditation body has access to any confidential information directly related to its official duties, including sanction recommendations that you forward to OIG. Unless the disclosure is an exception specified in 42 CFR 480.106, comply with the notification requirements in 42 CFR 480.105 before disclosing your information.

G. Disclosures to Other QIOs -- Disclose to another QIO information on patients and practitioners who are subject to review by the other QIO. Additionally, you may share identifiable data about patients, practitioners, or providers in your State with another QIO so long as that QIO applies the same confidentiality restrictions to your data that it is required to apply to its own.

H. Disclosures to Medical Review Boards -- Disclose to medical review boards established under §1881 of the Act information on patients, practitioners, and institutions receiving or furnishing end stage renal disease services.

10060 - Disclosure of QIO Information Involving Beneficiary Complaints

(Rev. 6, 08-01-03)

Section 1154(a)(14) of the Act requires you to conduct an appropriate review of all written complaints from Medicare beneficiaries or their designated representatives about the quality of Medicare services. Ensure that any disclosure of information is consistent with applicable provisions of 42 CFR Part 480.

10070 - Disclosure of QIO Information for Research Purposes -- Quality Review Study (QRS) Information

(Rev. 6, 08-01-03)

A. Independent Research Activities -- You cannot disclose information that explicitly identifies patients, practitioners, or your reviewers without their consent. You may disclose non-QRS information after deleting all confidential identifiers and any other information from which identification of an individual can be deduced. You may release de-identified information derived from information gathered as part of a QRS to individuals or organizations that demonstrate a need for this information. De-identified means that all explicit and implicit identifiers of patients, practitioners, providers, and health plans have been removed, encrypted, or otherwise modified to ensure that the identity of individuals or institutions may not be determined. Once the information has been de-identified, it becomes non-confidential and the requirements of 42 CFR 480.120(a)(8) and §10020 of the QIO Manual apply. Specifically, you must conform to the following conditions to have such information de-identified for release.

When requesting de-identification of QRS information for release, you must:

- Obtain prior approval from your Project Officer (PO).
- Conclude a Data Use Agreement (DUA) with the researcher prior to de-identification (See Exhibit 10-1 - Model Data Use Agreement). When it is completed, your PO should receive a copy.
- The DUA should specify both the length of time the researcher will need the data for the active analyses and, if applicable, the length of time you must retain the dataset following the active analyses (See below) (The intent of this requirement is to minimize the possibility that the researcher might mistakenly use the data for a purpose not covered by the Agreement).

- Request that the Standard Data Processing System (SDPS) contractor prepare the de-identified dataset. You may not independently de-identify data. Procedures for requesting the SDPS contractor's assistance are outlined in SDPS Memorandum 01-232-GN.

- At the request of the researcher and with the approval of your PO, request the SDPS contractor to link its data with other data provided by the researcher so long as all explicit and implicit identifiers are removed from the resulting dataset.

    - OR

- At the request of the researcher and with the approval of your PO, request the SDPS contractor to link its data with CMS data so long as all explicit and implicit identifiers are removed from the resulting dataset. For CMS datasets, the researcher does not have to provide an actual data file; however, the researcher must:

    - Submit a data request package to CMS Office of Information Services (OIS) for the CMS data that will be linked with the QIO data. The request package must include: a detailed request letter, project summary/protocol, proof of funding, and CMS DUA. If the project is Federally funded, it must also include a request/support letter from the Federal PO and the Federal PO must sign the CMS DUA. Additionally, provide OIS evidence of the approved QIO DUA.

    - Once the request has been reviewed and approved by OIS, OIS will notify the Office of Clinical Standards and Quality (OCSQ) of its approval. Once OIS approval for the use of the CMS data is confirmed, the SDPS contractor can perform the data pull and match.

- At the request of the researcher, archive the dataset in the offline electronic medium provided by the SDPS contractor for up to 5 additional years following the completion of the active analyses. This retention period must be specified in the DUA.

- If the user wishes to access the archived data for purposes of validating his conclusions, he must request a return of the dataset in writing. The request must specify the purpose for the request, the length of time needed for that purpose, and when the data will be returned.

- In the event that your contract with CMS is terminated prior to the termination of either the active analysis period or the retention period specified in the DUA, provide full documentation to the new QIO, which will conclude a new DUA with the researcher. If a new agreement is not concluded, the user forfeits all rights and privileges specified in this agreement and must return the data immediately.

- Maintain a record of all de-identified data provided and ensure that they are returned or destroyed as required in the DUA (The intent is to ensure that unneeded data are destroyed and not retained indefinitely).

- Should the same researcher wish to use the dataset for another project or should another researcher request the same dataset from you, prior to its release, you must conclude another DUA and provide your PO with a copy of that agreement.

- You may charge a fee for this service. This fee may not exceed the amount necessary to recover the cost to you and the SDPS contractor for providing the information (See 42 CFR 480.104(c)).

NOTE: This policy does not permit you to de-identify data provided by CMS for purposes of performing your contract (See Section H of your Contract).

B. Use of CMS-provided Data and/or Statutory Authority to Obtain Medical Records -- You may not use information provided by CMS or information acquired through the statutory authority to obtain medical records granted by your Contract for any purpose other than one specifically authorized by that Contract. For example, you may not use Medicare Provider Analysis & Review (MedPAR) or enrollment data obtained from CMS to provide a random sample for a researcher, nor may you use your Contract authority to obtain medical records and related information for purposes other than those provided for in that Contract.

If you request medical information in any capacity other than that of a QIO, as specified in your QIO contract with CMS, any request to a practitioner, provider, or beneficiary must clearly indicate that you are requesting the information outside your capacity as a QIO. Include the following language:

- "You are not required to provide the information requested in this letter. Neither your Medicare benefits nor your participation in the Medicare program will be affected should you decide not to participate."

This language is not required when a researcher is your employee (either part or full-time) and the activities being carried out relate directly to a Quality Improvement Project that you are conducting and which is funded by your QIO Contract.

C. Provider and/or Practitioner Ability to Designate an Agent to Receive Certain Information -- If a provider or practitioner, in writing, designates another party (e.g., corporate owner) as their agent for the receipt of specific data which they may obtain from you, you may, upon the written request of the provider(s) or practitioner(s), transmit the specified data to the agent either in lieu of or in addition to transmitting it to the provider(s) or practitioner(s). You must receive from the provider or practitioner both a designation of the agent and a request to send specific data to the agent. These items may be contained in the same written instrument (See Exhibit 10-2 - Model Letter). In

addition, when the requested data is sent to the agent, the agent must be advised of important information about re-disclosing data received from a QIO or Network (See Exhibit 10-3 - Model Language). You should inform your CMS PO of such arrangements and maintain adequate documentation of the arrangement. You may charge the reasonable costs of the disclosure in accordance with the provisions of 42 CFR 480.104(c).

D. DHHS Research Activities -- Research entities acting as employees or subcontractors of DHHS have access to your non-QRS confidential information when it is needed to accomplish DHHS' objectives. Provide this information in the manner and form required in accordance with 42 CFR 480.130.

10080 - Disclosure of QIO Sanction Information

(Rev. 6, 08-01-03)

As specified in 42 CFR 480.142, disclose sanction reports to OIG, CMS, and State and Federal agencies that investigate and prosecute fraud and abuse. Disclose relevant sanction information, including sanction reports, to licensing, certification, and accreditation bodies under the authority and limitations specified in 42 CFR 1004.70(c) and 480.138(a)(1).

Concurrent with your final notice, provide the affected practitioner or other person with a copy of the complete sanction report and recommendations that you are submitting to OIG (See §§9000-9070 and 42 CFR 1004.70(b)).

The sanction information that can be disclosed to licensing, certification, and accreditation bodies under the authority of 42 CFR 480.138(a)(1) includes only those portions of the file that the body needs to conduct its official duties (e.g., a synopsis of the particular case). Do not include the entire medical record or unnecessary information such as an overview of the sanction process. Determine, on a case-by-case basis, whether release of patient-specific information is appropriate.

10090 - Re-disclosure of QIO Information

(Rev. 6, 08-01-03)

A. Re-disclosure of Non-confidential Information -- There are no statutory or regulatory restrictions that limit a recipient's re-disclosure of your non-confidential information.

B. Re-disclosure of Confidential Information -- No recipient of your confidential information may re-disclose the information except under the limited circumstances authorized by 42 CFR 480.107.

Recipients of your confidential information (beneficiaries, practitioners, and providers) may re-disclose information about themselves provided the re-disclosure does not explicitly or implicitly identify another individual.

C. Notifying Recipients About Re-disclosing Confidential Information -- The regulation at 42 CFR 480.104(a)(2) requires you to inform recipients, in writing, that they cannot re-disclose confidential information you disclose to them except as permitted under 42 CFR 480.107. Your written notice should also advise the recipient of the penalties for unauthorized disclosures.

Explain in your notice to the recipient that, except as authorized in 42 CFR 480.107, confidential information cannot be re-disclosed unless the individuals who would be identified consent to the re-disclosure or all confidential personal identifiers are removed. The notice can be a separate attachment to the information provided, or you can include the notice in your response to the recipient.

As part of your responsibility to educate individuals and facilities about your review process (See 42 CFR 480.116), conduct activities that inform individuals and facilities in your area of the rules and restrictions applicable to confidential information. Improper re-disclosures of confidential information are generally inadvertent rather than intentional. Accordingly, provide educational programs to avoid problems.

Exhibit 10-1 - Model Data Use Agreement

(Rev. 6, 08-01-03)

Agreement for Use of Health Care Data:

In order to ensure the integrity, security, and confidentiality of information maintained by the (QIO Name), in compliance with their Medicare Quality Improvement Organization for (State Name) Contract #(Fill In) and with the confidentiality requirements as outlined in 42 CFR 480 and clause G.11 of their Contract, and to permit appropriate disclosure and use of such data as permitted by law, (QIO Name) and (Name of User) enter into this agreement to comply with the following specific paragraphs:

1. This agreement is by and between the (QIO Name), a Federally-designated Quality Improvement Organization under contract to the Centers for Medicare & Medicaid Services (CMS) Contract #(Fill In), and (Name of User) hereinafter termed "User."

2. This Agreement addresses the conditions under which (QIO Name) will disclose and the User will obtain and use the (QIO Name) data file(s) specified in paragraph 7. This agreement supersedes any and all agreements between the parties with respect to the use of the data from the files specified in paragraph 7 specified herein. Further, the terms of this Agreement can be changed only by a written modification to this agreement or by the parties adopting a new

agreement. The parties agree further that instructions or interpretations issued to the User concerning this Agreement or the data specified herein, shall not be valid unless issued in writing by the (QIO Name) point-of-contact specified in paragraph 5 or the (QIO Name) signatory to this Agreement shown in paragraph 24.

3. The parties mutually agree that (QIO Name) retains all ownership rights to the data file(s) referred to in this Agreement, and that the User does not obtain any right, title, or interest in any of the data furnished by (QIO Name).

4. The parties mutually agree that the following named individual is designated as "Custodian" of the file(s) on behalf of the User and will be personally responsible for the observance of all conditions of use and for establishment and maintenance of security arrangements as specified in this Agreement to prevent unauthorized use. The User agrees to notify (QIO Name) within 15 days of any changes of custodianship. The parties mutually agree that (QIO Name) may disapprove the appointment of a custodian or may require the appointment of a new custodian at any time.

    - (Name of Custodian) (Title of Custodian)
    - (Company/Organization)
    - (Street Address)
    - (City/State/ZIP Code)
    - (Phone Number - Including Area Code) (Email Address)

5. The parties mutually agree that the following named individual will be designated as "point-of-contact" for the Agreement on behalf of (QIO Name).

    - (Name of Contact) (Title of Contact)
    - (Company/Organization)
    - (Street Address)
    - (City/State/ZIP Code)
    - (Phone Number - Including Area Code) (Email Address)

6. The User represents and warrants, and in furnishing the data file(s) specified in paragraph 7 (QIO Name) relies upon such representation and warranty, that such data file(s) will be used solely for the following purpose(s): (The following material is included as an example)

    - To support HSPH's Agency for Healthcare Quality Research (AHQR) grant "Validating Guidelines for the Care of AMI Patients."

    - The User represents and warrants further that the facts and statements made in any study or research protocol or project plan submitted to the (Name of Funding Entity) for each purpose are complete and accurate. Further, the User represents and warrants that said study protocol(s) or

project plans, as have been approved by (Name of Funding Entity), represent the total use(s) to which the data file(s) specified in paragraph will be put.

- The User represents and warrants further that, except as specified in an Attachment to this Agreement or except as (QIO Name) shall authorize in writing, the User shall not disclose, release, reveal, show, or otherwise grant access to the data covered by this Agreement to any person. The User shall not sell, rent, lease, or loan the data covered by the Agreement to any person. The User agrees that, within the User organization, access to the data covered by this Agreement shall be limited to the minimum number of individuals necessary to achieve the purpose stated in this section and to those individuals on a need-to-know basis only.

- The User represents and warrants further that he shall not report any analyses that would require using either a patient, practitioner, or provider identifier (whether explicit or implicit) (e.g., physician specialty, hospital bed size, etc.) to obtain additional information.

7. The following (QIO Name) furnished data file(s) is/are covered under this Agreement: (The following material is included as an example)

    - File: Year(s):
    - CCP National Data Sample: 2/94 - 2/95
    - CCP National Data Sample: 2/95 - 7/95
    - Inpatient claims (Part A) for these beneficiaries identified in CCP National Data Sample including claims for the index AMI Admissions and all hospitalizations within a year of the index Admission: 1/1/93 - 12/31/96

8. The parties mutually agree that the aforesaid file(s) (and/or any derivative file(s)) may be retained by the User until (Enter Date), hereinafter known as the "end of active analyses date." Should the active analyses be completed before that date, the User agrees to notify (QIO Name) within 30 days of the completion of the active analyses for the purpose specified in paragraph 6.

    - The (QIO Name) agrees to archive an electronic, offline version of the data and resulting datasets for a period not to exceed 5 years from the completion of active analyses date and to provide the User with access to the data during that period. The User agrees to request access to the archived data in writing, to specify the purpose of the request and the length of time the data will be needed, and acknowledges that all provisions of this Data Use Agreement apply during any period in which he has access to the archived data (This paragraph to be inserted only in those cases where the User requests that the data be archived).

- At the end of the active analyses, (QIO Name) will notify the User either to return all data files to (QIO Name) at the User's expense or to destroy such data. If (QIO Name) elects to have the User destroy the data, the User agrees to certify the destruction of the files in writing within 30 days of receiving (QIO Name) instruction. A statement certifying this action must be sent to (QIO Name). If (QIO Name) elects to have the data returned, the User agrees to return all files to (QIO Name) within 30 days of receiving notice to that effect. The User agrees that no data, or any parts thereof, furnished by (QIO Name) shall be retained when the aforementioned file(s) are returned or destroyed unless authorization in writing for the retention of such file(s) has been received from the QIO's Project Officer and the person designated in paragraph 24 of this Agreement. The User acknowledges that stringent adherence to the date included in the first paragraph of Clause 8 is required, and that the User shall ask (QIO Name) for instructions under this paragraph if instructions have not been received after 30 days after the end of active analyses date.

- If the (QIO Name) and User have agreed that the data are to be retained, the QIO will destroy the data and datasets at or after the agreed-upon date for termination of the archiving period.

9. The User agrees to establish appropriate administrative, technical, and physical safeguards to protect the data and to prevent unauthorized use or access to it. The safeguards shall provide a level and scope of security that is not less than the level and scope of security established by the (QIO Name) Security and Confidentiality Policy (attached). The User acknowledges that the use of unsecured telecommunications, including the Internet, to transmit individually identifiable or deducible information derived from the file(s) specified in paragraph 7 is prohibited. Further, the User agrees that the data must not be physically moved or transmitted in any way from the site indicated in paragraph 4 without written approval from (QIO Name).

10. The User agrees that the authorized representatives of (QIO Name) will be granted access to premises where the aforesaid file(s) are kept for the purpose of inspecting security arrangements to confirm whether the User is in compliance with the security requirements specified in paragraph 9.

11. The User agrees that no findings, listing, or information derived from the file(s) specified in paragraph 7 may be released if such findings, listing, or information contains any combination of data elements that might allow the deduction of a beneficiary's, practitioner's, or provider's identification without first obtaining written authorization from the appropriate Project Officer or the person designated in paragraph 24 of this Agreement. Examples of such data elements include, but are not limited to, geographic indicator, age, sex, diagnosis, procedure, admission/discharge date(s), date of death, medical specialty, provider zip code, profit/non-profit status of provider, etc. The User agrees further that

(QIO Name) shall be the sole judge as to whether any finding, listing, information, or any combination of data extracted or derived from (QIO Name)'s files identifies or would, with reasonable effort, permit one to identify a beneficiary, practitioner, or provider or to deduce the identity of a beneficiary, practitioner, or provider to a reasonable degree of certainty.

12. The User agrees that, absent express written authorization from the appropriate Project Officer or the person designated in paragraph 24 of this Agreement to do so, the User shall make no attempt to link records included in the file(s) specified in paragraph 7 to any other identifiable source of information. This includes attempts to link to other (QIO Name) data file(s). The inclusion of linkage of specific files in a study protocol approved in accordance with paragraph 6 is considered express written authorization from (QIO Name).

13. The User agrees to submit to (QIO Name) a copy of all findings within 30 days of making such findings. The parties mutually agree that the User has "made findings" with respect to the data covered by this Agreement when the User prepares any report or other writing for submission to any third party (including, but not limited to, any manuscript to be submitted for publication) concerning any purpose specified in paragraph 6 (regardless of whether the report or other writing expressly refers to such purpose, to (QIO Name) or the files specified in paragraph 7 or any data derived from such files). The User agrees to submit such findings to CMS and the (QIO Name) 30 days prior to submitting them to any third party. The User agrees further to submit its findings to (QIO Name) within 30 days of receiving notice from (QIO Name) to do so.

14. The User agrees to include the following statement in any report of findings:

    - "The author acknowledges the assistance of the (QIO Name) and the Centers for Medicare & Medicaid Services (CMS) in providing data which made this research possible. The conclusions presented are solely those of the author and do not represent those of (QIO Name) or CMS."

15. The User understands and agrees that they may not reuse original or derivative data file(s) without prior written approval from the appropriate Project Officer or the person designated in paragraph 24 of this Agreement.

16. The parties mutually agree that the following specified Attachments are part of this Agreement.

17. The User agrees that in the event (QIO Name) determines or has a reasonable belief that the User has made or may have made disclosure of the aforesaid file(s) that is not authorized by this Agreement or other written authorization from the appropriate Project Officer or the person designated in paragraph 24 of this Agreement, (QIO Name), in its sole discretion, may require the User to:

- Promptly investigate and report to (QIO Name) the User's determination regarding any alleged or actual unauthorized disclosure;

- Promptly resolve any problems identified by the investigation to the satisfaction of the QIO's Project Officer;

- If requested by (QIO Name), submit a formal response to an allegation of unauthorized disclosure;

- If requested by (QIO Name), submit a corrective action plan with steps designed to prevent any future unauthorized disclosures; and

- If requested by (QIO Name), return data files to (QIO Name).

18. The User understands that as a result of (QIO Name)'s determination or reasonable belief that unauthorized disclosures have taken place, (QIO Name) may refuse to release further data to the User for a period of time to be determined by (QIO Name). The User further understands that (QIO Name) will advise other QIOs of the situation and enlist their participation in this refusal to release data to the User.

19. The User hereby acknowledges that if the information specified in this agreement is being utilized for research purposes supported by an award of an agency of the Department of Health & Human Services (DHHS), and if the User materially fails to fulfill its confidentiality obligations under the terms of its award agreement with that agency, DHHS has the authority under 45 CFR Part 74 to temporarily withhold cash payments, disallow funding and matching credit for all or part of the cost of the grant activity, suspend or terminate the grant in whole or in part, withhold further awards for the grant project or program, and other available legal remedies (See 45 CFR 74.62(a)(1)-(5)). DHHS officials may also attach special award conditions on future grants when a grantee has not conformed to the terms and conditions of a previous award, or "is not otherwise responsible" (See 45 CFR 74.14(a)(4)-(5)), and may place the name of the grantee on a "Departmental Alert List," to be consulted by all DHHS Grants Management Officials and program officials prior to awarding grants (See Grants Policy Directive Part 2.01.C.1). The strongest sanctions available to a DHHS agency responding to grantee misconduct are debarment or suspension, which preclude a grantee from receiving awards not just from DHHS, but government-wide (See 45 CFR 74.13).

20. If (QIO Name) ceases to serve as a QIO contractor before the expiration of the term of this agreement, (QIO Name) shall provide a copy of this agreement and all data or datasets in its possession to the successor QIO. It is the parties' understanding that, should (QIO Name) cease to serve as the QIO for (Name of State) before the expiration of the term of this agreement, the Centers for Medicare & Medicaid Services will direct the successor QIO to execute a new Data Use Agreement prior to the cessation of (QIO Name) Agreement containing

terms and conditions substantially identical to those contained herein. The User agrees to execute a new Data Use Agreement prior to the cessation of the contract between the Centers for Medicare & Medicaid Services and (QIO Name). Upon a failure to timely execute a new agreement, the User shall return any data or datasets in the User's possession to (QIO Name).

21. By signing this Agreement, the User agrees to abide by all provisions set out in this Agreement for protection of the data file(s) specified in paragraph 7, and acknowledges having received notice of potential penalties for violation of the terms of the Agreement.

22. On behalf of the User, the undersigned individual hereby attests that he or she is authorized to enter into this Agreement and agrees to all the terms specified herein.

    - (Name of Authorized Individual) (Title of Authorized Individual)
    - (Company/Organization)
    - (Street Address)
    - (City/State/ZIP Code)
    - (Phone Number - Including Area Code) (Email Address)
    - (Signature) (Date)

23. The Custodian, as named in paragraph 4, hereby acknowledges his/her appointment as Custodian of the aforesaid file(s) on behalf of the User, and agrees personally and in a representative capacity to comply with all of the provisions of this Agreement on behalf of the User.

    - (Name of User)
    - (Signature) (Date)

24. On behalf of (QIO Name), the undersigned individual hereby attests that he or she is authorized to enter into this Agreement and agrees to all the terms specified herein.

    - (Name of (QIO Name) Representative)
    - (Title of (QIO Name) Representative)
    - (Signature) (Date)

Exhibit 10-2 - Model Letter

(Rev. 6, 08-01-03)

Request for a QIO or ESRD Network to Disclose Information to a Facility's Agent:

[Name of Provider/ESRD Facility] (the Facility) has entered into an agreement, in accordance with State law, with [Name of Corporate Owner] for [Name of Corporate Owner] to serve as the agent (the Agent) of the Facility for purposes of receiving certain kinds of data on the Facility's behalf from [Name of the Quality Improvement Organization/ESRD Network]. The Agent is subject to the same requirements under Federal law as the Facility for purposes of receiving and re-disclosing the data. I request that [Name of Quality Improvement Organization/ESRD Network] send the following data to the Agent.

(List Specific Reports) for provider number _____

I have designated [Name of the Corporate Owner] as the Agent for the purpose described above for a period of 3 years from the date of my signature unless this designation is rescinded in writing before that date.

[Signature of Facility Administrator]

Attachment

Exhibit 10-3 - Model Language

(Rev. 6, 08-01-03)

Important Information About Re-disclosing Data Received from a Quality Improvement Organization or ESRD Network:

Under Federal law, a Quality Improvement Organization or ESRD Network must hold in confidence and not disclose to any person data or information that it has acquired in exercising its duties and functions, except as provided under various specific exceptions that appear in §1160 of the Social Security Act (the Act) (42 U.S.C. §1320c-9), the Quality Improvement Organization confidentiality regulations in 42 CFR part 480 and accompanying Manual Provisions.

A Quality Improvement Organization or ESRD Network can provide to an Agent only that data which it is authorized to disclose to the Facility under Federal law.

There are specific limitations on re-disclosing any data received from a Quality Improvement Organization or ESRD Network under §1160 of the Act and in 42 CFR §§480.107 and 480.140. Any person who discloses information not authorized under these provisions will, if convicted, be subject to a fine of up to $1000, or be imprisoned for no more than 6 months, or both, and will pay the costs of prosecution.