SUBJECT: Update to Pub. 100-10, Chapters 04 and 07 to Provide Language-Only Changes for Updating ICD-10

I. SUMMARY OF CHANGES: This Change Request (CR) contains language-only changes for updating ICD-10 language in Pub 100-10, Chapters 04 and 07. Additionally, references to CMS contractor types have been replaced with Medicare Administrative Contractors (MACs) in the sections that are updated by this transmittal. There are no new coverage policies, payment policies, or codes introduced in this transmittal. Specific policy changes and related business requirements have been announced previously in various communications.

EFFECTIVE DATE: Upon Implementation of ICD-10
*Unless otherwise specified, the effective date is the date of service.

IMPLEMENTATION DATE: Upon Implementation of ICD-10

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-Only One Per Row.

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III. FUNDING:
For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC statement of Work. The contractor is not obliged to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Manual Instruction
Quality Improvement Organization Manual
Chapter 4 - Case Review

4130 - DRG Validation Review -

Perform DRG validation on PPS cases (including hospital-requested higher-weighted DRG assignments), as appropriate (see §1866(a)(1)(F) of the Act and 42 CFR 476.71(a)(4)). Review the medical record for medical necessity and DRG validation (You are also required to perform a quality review if you believe that there may be a potential quality of care concern). The purpose of DRG validation is to ensure that diagnostic and procedural information and the discharge status of the patient, as coded and reported by the hospital on its claim, matches both the attending physician's description and the information contained in the patient's medical record. Refer the case for a physician review if medical judgment is needed when changing the narrative diagnosis that the codes were based upon. Your reviewer must use his or her professional judgment and discretion in considering the information contained on a hospital’s physician query form along with the rest of the medical record. If the physician query form is leading in nature or if it introduces new information, the non-physician reviewer must refer the case to the physician reviewer.

NOTE: For PPS waived/excluded areas, follow the instructions in your contract rather than these procedures.

A. Coding

Designate a Registered Records Administrator (RRA) or Accredited Records Technician (ART) as the individual responsible for the overall DRG validation process. Use individuals trained and experienced in Medicare diagnosis and procedure coding to perform the DRG validation functions. The validation is to verify the accuracy of the hospital's coding of all diagnoses and procedures that affect the DRG.

Base your DRG validation upon accepted principles of coding practice. Be consistent with guidelines established for ICD coding, the Uniform Hospital Discharge Data Set data element definitions, and coding clarifications issued by CMS. Do not change these guidelines or institute new coding requirements that do not conform to established coding rules.

Verify a hospital's coding in accordance with the coding principles reflected in the current edition of the ICD Coding Guidelines, and the official National Center for Health Statistics and CMS addenda, which update the guidelines annually. The annual addenda are effective on October 1 of each year and apply to discharges occurring on or after October 1. Use only these guidelines and updates when performing DRG validation.
Hospitals are not required to code minor diagnostic and therapeutic procedures (e.g., imaging studies, physical, occupational, respiratory therapy), but may do so at their discretion.

B. Diagnoses

Ensure that the hospital reports the principal diagnosis and all relevant secondary diagnoses on the claim. The relevant diagnoses are those that affect DRG assignment. See §20.2.2 in Chapter 3 of the Claims Processing Manual for procedures for reporting diagnoses and procedures at: http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf

The hospital must identify the principal diagnosis when secondary diagnoses are also reported. When a comorbid condition, complication, or secondary diagnosis affecting the DRG assignment is not listed on the hospital's claim but is indicated in the medical record, insert the appropriate code on the claim form. If the hospital already reported the maximum number of diagnoses, delete a code that does not affect DRG assignment, and insert the new code.

You are not required to place additional diagnoses on the claim as long as all conditions that affect the DRG are reflected in the diagnoses already listed, and the principal diagnosis is correct and properly identified. The hospital can list the secondary diagnoses in any sequence on the claim form because the GROUPER program will search the entire list to identify the appropriate DRG assignment.

- Principal Diagnosis -- Determine whether the principal diagnosis listed on the claim is the diagnosis which, after study, is determined to have occasioned the patient's admission to the hospital. The principal diagnosis (as evidenced by the physician's entries in the patient's medical record) (see 42 CFR 412.46) must match the principal diagnosis reported on the claim form. The principal diagnosis must be coded to the highest level of specificity. For example, a diagnosis reporting symptoms or signs may not be used as the principal diagnosis when the underlying cause of the patient's condition is known.

- Inappropriate Diagnoses -- Exclude diagnoses relating to an earlier episode that have no bearing on the current hospital stay. Delete any incorrect diagnoses and revise the DRG assignment as necessary.

C. Procedures

Ensure that the hospital has reported all procedures affecting the DRG assignment on the claim. If there are more procedures performed than can be listed on the claim, verify that those reported include all procedures that affect DRG assignment, and that they are coded accurately.

You are not required to place additional procedures on the claim as long as all procedures affecting the DRG assignment are listed on the claim. If the hospital reported the maximum six procedures and you need to add one that affects DRG assignment, delete a code that has no effect and insert the new code.
D. Guidelines for DRG Validation Review

Apply the following guidelines when conducting DRG validation review:

- Your validation of the claim confirms the principal diagnosis, secondary diagnoses, procedures, and the discharge status. The patient's age and sex need not be verified because these items are verified by the A/B MAC (A)'s edits before your DRG validation. If you find an error in discharge status or make corrections to the diagnosis or procedure information that affect the DRG, report the necessary information to the A/B MAC (A);

- Individuals with training and experience in ICD diagnosis and procedure coding are to review issues that involve technical coding changes or professional coding judgment;

- Do not make changes that do not require referral to a physician reviewer (e.g., technical coding changes) when the change has no effect on DRG assignment;

- Do not add diagnosis and procedure information to a claim when the addition would have no effect on the DRG assignment;

- Do not notify the involved hospital or physician of errors identified during the DRG validation process when the errors have no effect on DRG assignment;

- Refer to a physician reviewer issues that involve changes to diagnosis or procedure narrative descriptions or codes only when resolution of an issue requires a physician's medical judgment and the related change would affect DRG assignment;

- Do not refer a coding issue to a physician reviewer when the resulting change would have no effect on DRG assignment. Instead, take no action on the suspected coding error because a conclusion cannot be reached without a physician's involvement;

- When a correction that would affect DRG assignment requires the professional judgment of a physician reviewer and the case involves care provided by a health care practitioner other than a physician, ensure that the physician reviewer consults with a peer of the affected practitioner before making a determination;

- Before making a correction that affects DRG assignment, notify the involved provider and the patient's attending physician (or other attending health care practitioner), and provide an opportunity for discussion as specified in §4530. When a case is also questioned for both DRG changes and quality concerns, do not send notices at separate times. Notices are to be sent to comply with the quality review completion timeframes (see Exhibit 4-1A);
• After satisfying the requirement to offer an opportunity for discussion, notify the involved parties of the changes you are making to diagnostic and procedural information, as instructed in §§7100-7115; and

• Process any request for a re-review according to instructions contained in §7300. A provider or practitioner dissatisfied with the QIO’s change that results in a lower payment may request a re-review to the QIO.

**NOTE:** Inclusion of physicians in the DRG validation process is consistent with the intent of the acknowledgment statement required by 42 CFR 412.46, which is to make physicians accountable for their role in the payment process. The physician could be partially responsible for the incorrect DRG; thus, it is useful to notify him or her of this matter. Further, it may be useful for the QIO to hear the physician's viewpoint prior to changing the DRG assignment.
A. Format of Notice

Make your denial notices understandable and write the notices in "plain English." In addition, make sure that the beneficiary notice:

- Is in letter format;
- Is addressed to the beneficiary or his/her representative, if applicable (Where the beneficiary is deceased, address the notice to the beneficiary's representative or estate);
- Has a personalized salutation line (e.g., "Dear Mr. Smith" instead of "Dear beneficiary" or "Dear representative"); and
- Includes all pertinent information in the body of the notice (i.e., attachments or enclosures are not acceptable if they are in lieu of required information).

B. Identifying Information

The heading of the notice must include:

- The date of notice;
- The beneficiary's name;
- The beneficiary's Medicare Health Insurance Claim (HIC) Number;
- The beneficiary's address, his/her representative's address, or address of the person handling the beneficiary's estate if beneficiary is deceased;
- The provider's name;
- The provider's Medicare number (not necessary if you transfer notices to the A/B MAC (A) electronically);
- The medical record number (if known);
- The admission date (for denials related to "deemed" admission date cases, use the actual admission date); and
• The attending physician's name (for the services in question).

C. Specificity of Notice

The body of the notice must include:

• Identification of QIO -- Include a brief statement concerning your duties and functions under the Act.

• Reason for Admission -- Specify the reason for the admission. For partial denials (i.e., part of the stay is covered), include a statement specifying that the admission was medically necessary and appropriate (Do not include this statement in "deemed" admission date denial notices).

• Opportunity for Discussion -- Reference your discussions with the attending physician and provider. This requirement is met if your notice states that the involved physician and hospital were provided with an opportunity to discuss the case.

This applies to initial denial determinations and DRG assignment changes. When the DRG assignment is changed (either higher or lower), provide the hospital and physician an opportunity to discuss the DRG change.

• Solicitation of Views -- Reference your solicitation of the beneficiary's or his/her representative's views. Include the date of your discussion (This provision applies only when your review is based on a beneficiary's, his/her representative's, or provider's request for review of a continued-stay HINN).

• Reason for Denial -- Include the relevant facts explaining the reason(s) for the denial determination. The discussion in the beneficiary notice should be in layman's terms, and include all the information necessary to support the denial determination. The discussion must be specific to the individual case (i.e., it is unacceptable to state only that the services were medically unnecessary, inappropriate, or constituted custodial care).

  o For procedure denials, specify either that the patient requires the procedure but the services could be performed on an outpatient basis or that the patient did not require the surgery and, therefore, the procedure was not medically necessary (See Exhibit 7-28).

  o For deemed admission denials, continued-stay denials, day outlier denials, and partial admission denials (for non-PPS providers), specify the date(s)/period(s) for the stay or services that are not approved as being medically necessary or appropriate (A partial denial includes services/items that Medicare determined to be covered). In addition, for day outlier and partial admission denials (non-PPS providers), specify the total number of denied days (See Exhibits 7-26, 7-27, and 7-29).
• For continued-stay denials (related to HINNs) involving "deemed" admission situations, modify the notice to include the applicable language (e.g., reason for denial, periods approved and denied, liability determination) (See Exhibits 7-26 and 7-27).

• For cost outlier denials, specify the dates, charges, and specific services/items that will not be approved as being medically necessary or appropriate (See Exhibit 7-30).

• For day outlier denials, distinguish between those days that were not medically necessary and those where the beneficiary could have safely and effectively received the services on an outpatient basis.

• For changes to DRG coding information that affect the DRG assignment (either higher or lower), include a listing of the diagnosis and procedure codes and a narrative description as submitted by the provider and as changed by you along with the reason for the changes. Be as specific as possible in explaining the reason(s) for the changes (See Exhibit 7-31). Do not notify the hospital of changes to DRG coding information when the changes do not revise the DRG assignment.

• For billing errors, explain that the error precludes you from completing review of the case. Instruct the provider to submit an adjusted claim to the A/B MAC (A) (in accordance with your agreements with the A/B MAC (A) and provider) (See Exhibit 7-24).

• For circumvention of PPS denials, specify that you are denying the second admission. Explain whether the denial is based on services that should have been furnished during the first admission, on an inappropriate transfer from a PPS unit to a PPS-excluded unit, or on an inappropriate transfer from a PPS-excluded unit to a PPS unit. Cite the provision of the law that authorizes QIOs to deny payment for circumvention of PPS (See Exhibit 7-34).

• Liability Determination for the Beneficiary and Provider -- Include a statement of the beneficiary's or his/her representative's and the provider's liability determinations (under §1879 of the Act), including a detailed rationale for the decision (This applies only to initial medical necessity/custodial care denial determinations) (See Exhibit 7-20).

• For denials based on circumvention of PPS, explain that the limitation on liability provisions under §1879 do not apply, that the hospital is liable for the denied charges, and that the beneficiary or his/her representative is only responsible for payment of any applicable amounts for deductible, coinsurance, and convenience services and items normally not covered by Medicare (See Exhibit 7-34).

• If the beneficiary or his/her representative is found liable, specify the date of the prior notice. Include a copy of the notice. Do not include a
copy of the beneficiary's prior notice with the provider/physician notice unless the notice was issued by that provider.

- If the provider is found liable, specify the dates of liability (if applicable) and the source: brochures, prior notices (including dates), manual references, criteria, etc. Reference must be specific to individual case. Give the provider a copy of the source material referenced by you (See Exhibit 7-20, Conditions II, III, V, IX and X).

- For denials based on a beneficiary's or his/her representative's request for review of a continued-stay HINN or a provider's request for review of a proposed continued-stay HINN, include the date of your phone notification to the beneficiary or his/her representative (See Exhibit 7-20, Conditions VI and VII).

- For denials involving review of a HINN, do not approve payment for additional days under §1879 of the Act for purposes of post-discharge planning (i.e., grace days). A provider who issued a HINN has demonstrated knowledge that Medicare will not cover the services and, therefore, §1154(a)(2)(b) is not applicable (See Exhibit 7-20, Conditions VI and VII).

- For denials based on concurrent review not involving a HINN, you may approve payment for up to two additional days under §1879 of the Act for purposes of post-discharge planning (i.e., grace days) (See Exhibit 7-20, Condition VIII).

**NOTE:** When you deny a case that involves non-covered services such as routine foot or dental care, do not apply the provisions of §1879.

- **Liability Determination for the Physician --** Include a statement of the payment liability determination related to denied physician services (Under §§1842(l) and 1879 of the Act). Include a detailed rationale for the decision (Applies to hospital inpatient and ambulatory/outpatient surgical procedures/services and cost outlier(s) with physician component denials that are determined to be medically unnecessary).

- For denials involving claims for services billed on an assigned basis (whether furnished by Medicare participating or nonparticipating physicians), make your liability determination in accordance with the provisions of §1879 of the Act.

- For denials involving services billed on an unassigned basis (by nonparticipating physicians), make your liability determination in accordance with the provisions of §1842(l) of the Act.

**NOTE:** The determination as to whether the physician is protected from payment liability (when the physician accepts assignment) under §1879 of the Act or from making a refund to the beneficiary or his/her representative (when the physician does not accept assignment) under §1842(l) of the Act is made when the initial denial
decision is furnished. In both situations make a determination of the physician's and the beneficiary's knowledge of the non-covered services. Unless there is evidence to the contrary (e.g., the physician annotated in the medical record that he/she has given the beneficiary a written advance notice), presume that the beneficiary or his/her representative had no knowledge that Medicare would not pay for the denied items or services furnished by the physician. On a case-by-case basis, the physician may challenge this presumption when you offer the physician an opportunity to discuss the case. At the same time, ask the physician if he/she accepted assignment (if you were unable to determine this information from your review of the documents in the medical record). The physician should be able to provide you with the information you need as well as a copy of the written advance notice that he/she gave the beneficiary or his/her representative.

- Beneficiary Indemnification for Provider Services -- Include a statement related to the indemnification of the beneficiary or his/her representative when the provider has been found liable for the denied services.

Include the name, address, and telephone number of the A/B MAC (A, B, or HHHH) where the beneficiary or his/her representative can file a request for indemnification.

Inform the beneficiary that the following documents must be provided to the A/B MAC (A, B, or HHHH):

- A copy of the denial notice;
- A copy of the bill for the services; and
- A copy of the payment receipt from the provider or any other evidence showing that the beneficiary paid the provider.

Instruct the beneficiary that the request must be filed within 6 months of the date of your denial notice (See 42 CFR 411.402(a)(4)).

Specify that if the beneficiary or his/her representative and the provider are not held liable §§1879(a)(1) and (2) conditions are met, he/she is responsible only for payment of any deductible, coinsurance, and convenience services and items normally not covered by Medicare that are furnished during the admission (See Exhibit 7-20, Condition I).

In addition, specify that if the beneficiary or his/her representative is not held liable but the provider is held liable, he/she is responsible only for payment of any convenience services and items normally not covered by Medicare for the denied period. In this situation, the beneficiary or his/her representative is not responsible for the denied services including any applicable deductible and coinsurance (See Exhibit 7-20, Condition II).

- Beneficiary Indemnification for Physician Services -- Include a statement related to the indemnification of the beneficiary or his/her representative for
denied physician's services (e.g., inpatient procedure, cost outlier with a physician component, and ambulatory/outpatient surgical denials).

Include the name, address, and telephone number of the A/B MAC (B) where the beneficiary or his/her representative can file a request for indemnification.

Inform the beneficiary that the following documents must be provided to the A/B MAC (B):

- A copy of the denial notice;
- A copy of the bill for the services; and
- A copy of the payment receipt from the physician or any other evidence showing the beneficiary paid the physician.

Instruct the beneficiary that the request must be filed within 6 months of the date of your denial notice (See 42 CFR 411.402(a)(4)).

For denials involving services billed on an assigned basis by a Medicare participating or nonparticipating physician, specify that the beneficiary or his/her representative should contact the A/B MAC (B) for any refund (See Exhibit 7-20, Conditions III, XI, and XII).

For denials involving services billed on an unassigned basis by a nonparticipating physician, specify that the beneficiary or his/her representative should contact the physician for any refund (See Exhibit 7-20, Condition IIIA).

- **Beneficiary's Future Payment Liability --** Include a statement related to the liability for payment of denied services occurring in the future that involve the same, or reasonably comparable, conditions.

  This applies only to initial medical necessity/custodial (level of) care denial determinations.

  Do not include such a statement if the denial is for a procedure that cannot be repeated (e.g., total removal of an organ).

- **Reconsideration Rights --** Include a statement of the reconsideration rights (including expedited reconsideration, if applicable) of the beneficiary or his/her representative, provider, and attending physician (See Exhibit 7-21). This applies only to initial denial determinations.

  The statement must specify:

  - The places that the beneficiary or his/her representative may file a reconsideration (i.e., Social Security Administration (SSA) Office, Railroad Retirement Office, if applicable, or at your office);
• The time requirements to file a request; and

• The possible outcomes of your review as a result of a request for reconsideration.

Beneficiary Right To Legal Representation -- Include a statement informing the beneficiary or his/her representative of the options for obtaining attorney representation at any step of the appeal process, of the availability of free legal services organizations, and to contact the local social security office for additional information, if needed (See §206(c) of the Act). This requirement is applicable to QIOs involved in the Medicare program by 42 USC 1395(ii). This applies only to initial medical necessity/custodial (level of) care denial determinations.

Insert the following statement, which shall not be altered, after the reconsideration rights paragraph in all initial denials where the beneficiary or his/her representative receives your notification:

"If you want help with your appeal of this denial determination, you can have a friend, lawyer, or someone else help you. Some lawyers do not charge unless you win your appeal. There are groups, such as lawyer referral services, that can help you find a lawyer. There are also groups, such as legal aid services, who will give you free legal services if you qualify."

Beneficiary Right to Review the Medical Record -- Include a statement informing the beneficiary or his/her representative of the right to examine his/her complete medical record and to receive a copy of that record. This applies only to initial medical necessity/custodial (level of) care denial determinations.

Insert the following statement, which cannot be altered, after the beneficiary right to legal representation paragraph in all initial denials where the beneficiary or his/her representative receives your notification:

"You have the right to examine the complete medical record (and other pertinent information) that we relied upon in making this denial determination. Although the hospital is the official repository of the medical records relevant to stays in the facility, should you wish to examine the records and other pertinent information for this particular stay, contact us at the address or telephone number listed above. There is no charge to examine the material at our office. You may also request a copy of the medical record and other pertinent information. We will, however, charge you a reasonable fee for photocopying and mailing this information."

If the beneficiary or his/her representative requests the record, redact any QIO deliberations and the names of any QIO review coordinators, physician advisors, or consultants from the material before its release. All practitioner-specific information must be released. Disclose the names of all practitioners
who were involved in the patient's treatment and whose names appear in the medical record or other pertinent information.

NOTE: Do not make notations on pages of the medical record in order to minimize the amount of redacting required.

Provide the record at a reasonable cost. The cost is limited to the cost of copying, redacting, and mailing the information.

- Re-review Rights Related to DRG Assignment Changes -- Include a statement of the re-review or reopening rights of the provider and physician. Re-review or reopening rights do not apply when the DRG assignment does not change.

Specify the place to file a review (i.e., QIO).

Specify the time requirements for filing such a request.

NOTE: The re-review or reopening rights do not apply to coding changes that do not affect DRG assignment.

- Signature -- For denial notices include the signature, including title, of the QIO Medical Director or the signature of the QIO physician to whom the Medical Director has delegated this authority. If you delegate this authority to your physician reviewers, do so in accordance with the confidentiality regulations, which specify that the identity of the reviewer cannot be disclosed unless the individual gives his/her consent (See 42 CFR 476.101(b) and 133(a)(2)(iii)). The Billing Error Denial Notice (Exhibit 7-24) may also be signed by the QIO Chief Executive Officer (CEO) or appropriate designee. DRG assignment changes that do not involve medical judgment may also be signed by the Accredited Record Technician or Registered Record Administrator.


You are responsible for conducting DRG validation re-reviews. The authority for reviewing changes in diagnostic and procedural coding information is found in 42 CFR 478.10(c).

A. Applicability

Although there are no reconsideration or appeal rights available for changes resulting from DRG validation, the same process used for making a reconsideration determination is used for DRG re-reviews (See §7430). A provider or practitioner dissatisfied with your change to the diagnostic or procedural coding information is entitled to a review of that change if it caused an assignment of a different DRG and resulted in a lower payment (See 42 CFR 478.15(a)(1)). A beneficiary or his/her representative dissatisfied with your change of the diagnostic or procedural coding
information is also entitled to a review of that change if it caused an initial denial of a furnished service (See 42 CFR 478.15(a)(2)). Review each case in its entirety.

**B. How to Request a Re-review**

The party must file a written request within 60 calendar days after the date of receipt of the notice of change to the diagnostic or procedural coding information. A party may also file such a request after 60 days for good cause (See §7410.C).

**C. Qualifications of a Reviewer**

The individual who reviews changes in DRG procedural or diagnostic information must be a physician who meets the requirements in §7420.A. The individual who reviews changes in DRG coding must be qualified through training and experience with ICD coding. The reviewer (physician or non-physician) cannot be the person who made the initial determination (A Registered Records Administrator or Accredited Records Technician must have responsibility for the overall DRG validation process).

**D. Timing of Re-review**

Complete your re-review and send a written notice to all parties within 30 working days of receipt of the request for a re-review.

**E. Notices to Parties**

Notify all parties (in writing) of your re-review determination. Be specific in explaining the reason(s) for the changes (See Exhibit 7-47) (Do not send this notice to the beneficiary). Notices of re-review must contain the following elements:

- A brief statement concerning your duties and functions under the Act, including your responsibility to perform DRG validation;
- A listing of the ICD *diagnosis and procedure* code(s) and narrative description as submitted by the provider and as originally changed by you, along with the reason for the changes;
- A brief statement explaining that the provider and practitioner were given an opportunity to provide additional information;
- The rationale used in upholding or reversing the initial DRG determination, including the code(s) you finally determined to be correct upon re-review;
- A statement that the re-review determination is final (i.e., no further appeals apply); and
- The signature, including title, of the medical director or designated physician if the change(s) involve DRG procedural or diagnostic information (i.e., medical judgment). If the change(s) involve(s) DRG coding errors, the re-review notice may be signed by the medical director, designated physician,
Chief Executive Officer, Accredited Record Technician, or Registered Record Administrator (See §7115.C.15).