HINN 11 Instructions

I. Introduction

Historically, the only limitation of liability (LOL) notices for fee-for-service beneficiaries who are hospital inpatients have been the Hospital Issued Notices of Noncoverage (HINNs). LOL notices are required under §1879 of the Social Security Act (the Act) in order to hold beneficiaries liable for certain noncovered services. Basic information on LOL is given in Chapter 30 of the on-line Medicare Claims Processing Manual.

There are several different versions of the HINNs, but before 2006, none of them addressed the ability of hospitals to charge their inpatients for certain noncovered services severable from covered inpatient stays. The ability to charge beneficiaries for such items-- medically unnecessary diagnostic and therapeutic services-- during these covered stays is codified under regulations at 42 Code of Federal Regulations (CFR) 412.42(d). Note that the term "medically unnecessary" in these cases specifically means Medicare has made a coverage decision that the service(s) at issue is/are not reasonable or necessary under its own coverage policy in accordance with §1862(a)(1)(A) of the Act. It does not mean hospitals treating these patients believe such service(s) to be unnecessary, as providing completely unnecessary services would be unethical and potentially fraudulent.

HINN 11 has now been completed to fit this specific case for hospital inpatients. This HINN, and instructions for its use, are provided below.

NOTE: Hospitals may continue to opt NOT to charge beneficiaries for noncovered services, and must only give notice when planning to charge.

II. Use of HINN 11

Hospitals will only use HINN 11 when specific criteria are met. First, all criteria of regulations at 42 CFR 412.42 (d) must be in evidence, as follows:

- The item or service at issue must be a diagnostic or therapeutic service excluded from coverage as medically unnecessary, and
- The beneficiary must require continued hospital inpatient care.

When these conditions apply, any type of Medicare facility providing hospital-level inpatient care to beneficiaries under the Original Medicare program may use this notice.

Second, related to the first bullet above, HINN 11 is only used for items or services when there is published Medicare coverage policy-- national or local-- confirming the item or service is noncovered based on a medical necessity determination. Local policy is formulated by intermediaries; and intermediaries should be contacted for more information. National coverage policy can be found at the Centers for Medicare and Medicaid Services (CMS) coverage website at:

http://www.cms.hhs.gov/Medicare/Coverage/CoverageGenInfo/index.html

There is information at this site on how a national coverage determination can be obtained for any new procedure.

Finally, there are also Medicare payment policy requirements for use of this form. First, the inpatient stay must be covered, since if the stay was or had become noncovered, other notification requirements would apply (for example, HINN 1). Second, the item or service in question must not be bundled into or integral to payment or treatment for the diagnoses/reasons justifying the covered inpatient stay. If needed, hospitals should contact their intermediaries to assure item(s) or service(s) listed on HINN 11 are distinct from any care considered packaged into the inpatient stay.

III. Delivery of HINN 11

Delivery of HINN 11 must meet the basic delivery standards of other HINNs.

> **NOTE:** There is no period to wait before HINN 11 becomes effective, such as the 1-3 day period hospitals must wait after the delivery of other HINNs addressing entire stays. HINN 11 is immediately effective if understood and signed by the beneficiary or representative.

Current HINN instructions are found in 2005 CMS transmittal 594, Section V. of the attachment to the business requirements. In short, the hospital staff must go over the HINN letter with the beneficiary or representative before signature and assure that person understands the HINN before signing it. This HINN should be kept on file in medical records.

Providers must give a copy of the completed notice to beneficiaries, and must also give a copy to the beneficiary's attending physician. Copies must be given to intermediaries or Quality Improvement Organizations (QIOs) upon request.

IV. Model Language

Since all HINNs are produced in model language, they have not been subject to clearance under the Paperwork Reduction Act, and in fact pre-date that Act. With model language, the CMS cannot prohibit changes, but any adaptation of the model offered could lead to a finding that notice had been invalid. However, intermediaries are instructed only to make such a finding if the mandatory elements listed below in VII are either missing or unintelligible. Intermediaries do have limited discretion to find HINN 11 invalid for other reasons that they deem extraordinary/could not have been foreseen.

V. Completion of the HINN 11

General and HINN-11 specific form preparation and completion instructions follow.

A. General Instructions. As with comparable notices, legal or letter-size paper may be used for reproduction of this letter. All information should remain on the same page as it appears in this instruction, with the exception to go to a third page noted below. Hospitals should use the exact font given in the notice, Times New Roman, 12 point, if possible, or another as close to the font shown in these instructions as possible. The font should be at least 12 point in size, 18 point font for the title. A visually high-contrast combination of dark ink on a pale background must also be used. Do not use font effects, such as bolding, italicizing, or highlighting, other than those appearing in this instruction.

Entries for all blanks on the notices can be hand-written, but handwriting must be legible. The handwriting should be no smaller than approximately font size 10. If typing entries to the notice, font size 12 is recommended over 10, but 10 is permitted.

B. HINN-11 Specific Instructions. The model letter itself appears at the end of this attachment. Other general guidance for the reproduction of this specific letter:

- The letter is produced as a two-page document, but it may be produced as 3 pages if needed to complete the content requirements, such as additional lines for logos, long names or titles; however, new or superfluous content should not be added to the form.
- The form can be reproduced as two or more separate pages, or the front and back of the same page.
- Blanks in the letter are either labeled immediately under the blank as to what information should be entered, or instructions appear below on completion of unlabelled blanks in order of their appearance on the letter.
- Text in *SHADOWED SMALL CAPS* should be removed before reproducing the letter.
- The following detailed instructions for completing the letter are in three parts: the header section on the first page, the remainder of the first page, and the second page.

1. Header Section (Page 1 from Top to "*Insert Hospital Letterhead…*")

Retain the HINN 11 title. Remove the instruction about inserting the letterhead. Insert hospital letterhead, logo and/or basic contact information: hospital name, address and telephone number. If the letterhead or logo does not provide the contact information, it must be added.

2. Instructions for Completing Page 1 (Remainder of Page after Header)

Top Section. Complete the first box containing seven labeled blanks: the name of the patient or representative and two blanks for his/her address information, his/her Medicare or health insurance claim (HIC) number, the date of the notice (the date it is given to the beneficiary or representative), the admission date of this hospital stay and name of the beneficiary's attending physician.

Middle Section. Each blank unlabelled in the letter itself is filled with a temporary reference to a Blank number and subject in *SHADOWED SMALL CAPS*. Remove these temporary references and then complete the first four unlabeled blanks as follows:

Blank 1	Insert the name(s) of the applicable medically unnecessary diagnostic or therapeutic service(s).
Blank 2	Specify the reason for noncoverage of these services, such as: "according to Medicare national coverage decision, this service is medically unnecessary".
Blank 3	Provide justification of the assessment of noncoverage by briefly describing and giving a citation to the appropriate Medicare coverage policies or guidelines.
Blank 4	Fill in the patient financial responsibility by giving the actual total dollar amount the beneficiary will be charged for this/these service(s).

Bottom Section. The boxed signature area at the end of the page should be completed by the beneficiary or representative when comprehending the notice after review with hospital staff. The beneficiary or representative must sign the boxed signature line at the end of the page, though hospital staff may enter the date for that person if needed.

3. Instructions for Completing Page 2

Top Section. The first part of this page gives a general description of the appeal rights available refunds required in accordance with 42 CFR 412.42(d). There are no blanks to complete in this section.

NOTE: There is no QIO immediate review/appeal option with HINN 11 as with other HINNs.

Lower Section. This section gives general information on the intermediary and QIO roles. Remove the temporary references in Blanks 5 and 6, and otherwise complete these blanks as follows:

Blank 5	Provide the name of the applicable Medicare intermediary and the 1-800-Medicare number for beneficiary questions.
Blank 6	Provide the name, address and telephone number of QIO for the State.

Final Signature. This is a blank for a signature from appropriate hospital personnel approving delivery of this notice. Having removed the temporary reference information in Blank 7, complete the blank as follows:

Blank 7	Have the appropriate hospital staff person, chairperson of the utilization review committee, etc., sign the line. Print the name and title of the person under the signature line.

VI. Procedures After Signature

HINN 11 documents the beneficiary or representative's consent to accept financial liability for a noncovered procedure, or procedures, unlike other HINNs that relate to entire stays. If in between signing HINN 11 and the actual procedure itself the beneficiary or representative changes his/her mind, or if the hospital decides against delivering the procedure for whatever reason, HINN 11 should be annotated appropriately and retained in the file.

Funds may be collected after the form is signed, but beneficiaries should be advised in advance if hospitals plan to collect funds prior to discharge. If the service(s) in question are found to be covered, all related monies collected from the beneficiary must be refunded.

VII. Oversight

Unlike other HINNs, there will not be automatic review of HINN 11 by QIOs. Intermediaries will have primary oversight of provider use of this HINN, as opposed to QIOs. With HINN 11, QIOs will exercise medical judgment by reviewing this new HINN and related cases only when specifically requested by the involved beneficiary, beneficiary representative, or intermediary. Intermediaries make such requests of QIOs as needed to avoid duplicating QIO expertise on medical necessity relative to hospital inpatients.

Intermediaries will not perform universal or automatic review of this HINN either, especially since all uses of this model letter must relate to published Medicare national or local coverage decisions/policy on the service(s) at issue that confirm noncoverage. Intermediaries will usually only review HINN 11 in the following cases:

- If a beneficiary or beneficiary representative makes a related complaint,
- If appropriate to the development of a related claim, and
- If getting a referral from a QIO.

An intermediary has the discretion to review for other reasons, such as if receiving a related complaint or performing related investigation of the provider who gave notice, but an intermediary is not obligated to perform review under circumstances other than those listed above. If requests for review are not made, and if the intermediary does not review for another reason, the notice will be considered valid, and the validity can only be revisited if a related claim appeal is filed.

When reviewing HINN 11, intermediaries only determine if adequate notice was given and related instructions were followed. Review may be similar to that done for other liability notices, such as the Advance Beneficiary Notice (ABN). At minimum, the intermediary will assure the HINN 11 model language letter conveys the following information:

- The basis of the determination that inpatient hospital care is not necessary or reasonable (i.e., coverage exclusions) based on published Medicare coverage policy;
- The determination is the hospital's opinion, which Medicare can confirm by making a payment determination on a related claim;
- Customary charges will be made if the beneficiary receives the services for which the beneficiary will be liable;
- The beneficiary may request the intermediary or QIO review the validity of the hospital's opinion if the beneficiary receives the services (the QIO only when medical judgment is involved); note the intermediary performs such review by adjudicating the related claim, and the QIO only when contacted by the beneficiary, responding to the beneficiary and relaying any actionable findings to intermediary;
- Any determination made by the intermediary or the QIO may be appealed by the beneficiary though the standard claims appeal process, and the letter notes the hospital, and the attending physician when acting for the beneficiary, also appeal through this process as in noted in 42 CFR 412.42 (d); and
- Any charges for the services will be refunded if they are found to be covered by Medicare.

The intermediary will also assure that the hospital’s use of the notice conforms to the requirements of II. above.