# Medicare Coverage & Billing for Clinical Research: Definitions, Requirements & Authorities

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<th>TOPIC</th>
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<tr>
<td><strong>“Approved Study”</strong></td>
<td>NOT DEFINED. Term introduced with new Q0 and Q1 modifiers.</td>
<td>Transmittal 1418 (CR 5805) Jan. 18, 2008</td>
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<td><strong>“Clinical Research”</strong></td>
<td>PROPOSED ONLY. CURRENT J JULY 2007 CTP does NOT include definition of clinical research. “Clinical Research” means any systematic investigation involving human participants which is designed to contribute to generalizable knowledge and which involves a clinical intervention, care delivery strategy, or diagnostic technique designed to potentially improve predefined health outcomes.</td>
<td>July 19, 2007 Proposed Decision Memorandum (CAG-00071R2)</td>
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| **“Deemed Study”**             | • funded by the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Agency for Healthcare Research and Quality (AHRQ), CMS, Department of Defense (DoD), and the Department of Veterans Affairs (VA);  
• supported by centers or cooperative groups funded by the NIH, CDC, AHRQ, CMS, DoD and VA;  
• conducted under an investigational new drug application (IND) reviewed by the FDA; or  
• a drug trial exempt from the need for an IND under 21 C.F.R. § 312.2(b)(1). | July 9, 2007 National Coverage Decision Routine Costs in Clinical Trials (“CTP”)  
Medicare National Coverage Determinations Manual, Pub. 100-03, Ch. 1, Part 4, sec. 310 [Clinical Trials] |
| **“Device”**                   | The Food and Drug Administration (FDA) defines a medical device as: An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:  
• Recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,  
• Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or  
• Intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes. | FD&C Act, sec. 201(h), 21 USC 321(h) [Definitions] |
| **“Drug”**                     | • “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” and “articles (other than food) intended to affect the structure or any function of the body of man or other animals” | FD&C Act, sec. 201(q)(1), 21 USC 321(q)                                      |
| **“Humanitarian Use Device” (“HUD”)** | a “medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year.” | 21 CFR 814.3(m) [PreMarket Approval - Definitions]                           |
| **“Humanitarian Device Exemption” (“HDE”)** | An HDE is an application that is similar to a PMA application, but is exempt from the effectiveness requirements of sections 514 and 515 of the Food, Drug, and Cosmetic Act (the Act). FDA approval of an HDE authorizes an applicant to market a HUD, subject to certain profit and use restrictions set forth in section 520(m) of the Act. HUDs cannot be sold for profit except in narrow circumstances and they can only be used in a facility after an IRB has approved their use in that facility, except in certain emergencies. | FDA Draft Guidance for HDE Holders (Aug 2008)                              |
| **“IDE” required**             | An investigational device exemption (IDE) is required to do the following:  
• Investigate (in a clinical study) an unapproved “significant risk” device. [The majority of IDE studies are conducted to collect safety and effectiveness data used to support a Premarket Approval (PMA) applications].  
• Investigate a legally marketed device for a new indication. | See generally 21 CFR Part 812                                                |
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<td>&quot;IDE Exempt&quot;</td>
<td>Device studies exempt from IDE regulations generally include:&lt;br&gt;• Pre-1976 devices&lt;br&gt;• Investigations conducted with legally marketed devices (e.g., 510(k) cleared and HDE- or PMA-approved), <strong>if used in accordance with the approved labeling</strong> (May include consumer preference testing of marketed device or combinations of legally marketed devices)&lt;br&gt;• Studies using in vitro diagnostics labeled for “research purpose only” as per regulations 21 CFR 809.10(c) and if the testing: (1) is non-invasive, (2) does not require invasive sampling procedures that present significant risk; (3) does not introduce energy into a subject; AND (4) is not used as a diagnostic procedure without confirmation by another medically established diagnostic product or procedure&lt;br&gt;• custom devices (narrowly defined)&lt;br&gt;• foreign studies; declaration of Helsinki</td>
<td>• 21 CFR 812.2(c)</td>
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<td>&quot;Immediately Life Threatening&quot;</td>
<td>“a stage of the disease in which there is a reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment.” [NOTE: CMS guidance indicates that CMS has adopted the FDA definition of “immediately life threatening”]</td>
<td>• MLN Matters #MM354, July 3, 2005&lt;br&gt;• 21 CFR Sec. 812.36 [Definition of I immediately life threatening]</td>
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<td>&quot;Investigational new drug&quot;</td>
<td>Investigational new drug means a new drug or biological drug that is used in a clinical investigation. The term also includes a biological product that is used in vitro for diagnostic purposes. The terms “investigational drug” and “investigational new drug” are deemed to be synonymous&lt;br&gt; (p) The term “new drug” means&lt;br&gt; (1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the condition prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a “new drug” if at any time prior to the enactment of this Act [enacted June 25, 1938] it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or&lt;br&gt; (2) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.</td>
<td>• FD&amp;C Act, sec. 201(h), 21 USC 321(b)</td>
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<td>&quot;IND Exempt&quot;</td>
<td>(b) Exemptions: (1) The clinical investigation of a drug product that is lawfully marketed in the United States is exempt from the requirements of this part if all the following apply: &lt;br&gt; (i) The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug; &lt;br&gt; (ii) If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product; &lt;br&gt; (iii) The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product; &lt;br&gt; (iv) The investigation is conducted in compliance with the requirements for institutional review set forth in part 56 and with the requirements for informed consent set forth in part 50; and &lt;br&gt; (v) The investigation is conducted in compliance with the requirements of § 312.7.</td>
<td>• 21 CFR 312.2(b)(1) [Exemptions to Investigational new drug requirements]</td>
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<td>&quot;Medically indigent&quot;</td>
<td>Patients whose health insurance coverage, if any, does not provide full coverage for all their medical expenses and that their medical expenses, in relationship to their income, would make them indigent if they were forced to pay full charges for their medical expenses</td>
<td>• MLN Matters #SE0822, September 30, 2008*</td>
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| “Qualified Study” | Meets “3 Requirements” and is “deemed” to have 7 “highly desirable characteristics” | • July 9, 2007 National Coverage Decision Routine Costs in Clinical Trials (“CTP”)  
• Medicare National Coverage Determinations Manual, Pub. 100-03, Ch. 1, Part 4, sec. 310 [Clinical Trials] |
| “3 Requirements” | • **Evaluates a Medicare Benefit** — The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians’ service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., eyeglasses or hearing aids).  
• **Has a Therapeutic Intent** — The trial must be intended to test an item or service intended to help patients (e.g., it is not solely to measure toxicity or disease pathology).  
• **Enrolls Diagnosed Beneficiaries** — Trials of therapeutic interventions must enroll patients with diagnosed diseases rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group. | • July 9, 2007 National Coverage Decision Routine Costs in Clinical Trials (“CTP”)  
• Medicare National Coverage Determinations Manual, Pub. 100-03, Ch. 1, Part 4, sec. 310 [Clinical Trials] |
| “7 highly desirable characteristics” | • The principal purpose of the trial is to test whether the intervention potentially improves the participants’ health outcomes.  
• The clinical trial:  
  o is well-supported by available scientific and medical information or is intended to clarify or establish the health outcomes of interventions already in common clinical use;  
  o does not unjustifiably duplicate existing studies;  
  o is appropriately designed;  
  o is sponsored by a credible organization or individual capable of successfully executing the proposed trial; and  
  o complies with federal regulations regarding human subjects.  
• All aspects of the trial are conducted according to the appropriate standards of scientific integrity. | • July 9, 2007 National Coverage Decision Routine Costs in Clinical Trials (“CTP”)  
• Medicare National Coverage Determinations Manual, Pub. 100-03, Ch. 1, Part 4, sec. 310 [Clinical Trials] |
| “related to” | **NOT Defined by statute or regulation.** Following are examples of services “related to” and “not related to” noncovered services while the beneficiary is an inpatient:  
• A beneficiary was hospitalized for a noncovered service and broke a leg while in the hospital. Services related to care of the broken leg during this stay is a clear example of “not related to” services and are covered.  
• A beneficiary was admitted to the hospital for covered services, but during the course of hospitalization became a candidate for a noncovered transplant or implant and actually received the transplant or implant during that hospital stay. When the original admission was entirely unrelated to the diagnosis that led to a recommendation for a noncovered transplant or implant, the services related to the admitting condition would be covered.  
• A beneficiary was admitted to the hospital for covered services related to a condition which ultimately led to identification of a need for transplant and receipt of a transplant during the same hospital stay. If, on the basis of the nature of the services and a comparison of the date they are received with the date on which the beneficiary is identified as a transplant candidate, the services could reasonably be attributed to preparation for the noncovered transplant, the services would be “related to” noncovered services and would also be noncovered. | • 60 Fed Reg 48417, 4820 (Sept. 19, 1995)  
• Medicare Benefit Policy Manual (Pub. 100-2), Ch. 16, sec.180 [Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare] |
### TOPIC: Definition/Requirement

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<tr>
<td>&quot;Routine costs&quot;</td>
<td>• July 9, 2007 National Coverage Decision Routine Costs in Clinical Trials (&quot;CTP&quot;)&lt;br&gt;• Medicare National Coverage Determinations Manual, Pub. 100-03, Ch. 1, Part 4, sec. 310 [Clinical Trials]</td>
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<tr>
<td>&quot;Significant Risk Device&quot;</td>
<td>• 21 CFR Sec. 812.3(m)&lt;br&gt;• FDA Overview of Significant Risk vs NSR Devices&lt;br&gt;• FDA Information Sheet Guidance (SR vs NSR, including examples)</td>
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<td>&quot;Therapeutic Intent&quot;</td>
<td>• July 9, 2007 National Coverage Decision Routine Costs in Clinical Trials (&quot;CTP&quot;)&lt;br&gt;• Medicare National Coverage Determinations Manual, Pub. 100-03, Ch. 1, Part 4, sec. 310 [Clinical Trials]</td>
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<td>&quot;Usual Patient Care&quot;</td>
<td>• Medicare Provider Reimbursement Manual, Pub. 15-1, Ch. 5, sec. 502.2&lt;br&gt;• Medicare Provider Reimbursement Manual, Pub. 15-1, Ch. 5, sec. 504.1&lt;br&gt;• NIH Grants Policy Statement (03/01) Research Patient Care Costs</td>
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### General Coverage Principles

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<th>Item or service fits a Medicare Benefit Category</th>
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<tr>
<td>Item or service fits a Medicare Benefit Category (e.g., physicians' service, durable medical equipment, diagnostic test)</td>
<td>• July 9, 2007 National Coverage Decision Routine Costs in Clinical Trials (&quot;CTP&quot;)&lt;br&gt;• Medicare National Coverage Determinations Manual, Pub. 100-03, Ch. 1, Part 4, sec. 310 [Clinical Trials]&lt;br&gt;• SSA sec. 1812 [Part A], 42 USC 1395d&lt;br&gt;• SSA sec. 1832 [Part B], 42 USC 1395k&lt;br&gt;• See generally Medicare Benefit Policy Manual, Pub. 100-2</td>
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<td><strong>Item or service is reasonable and necessary</strong></td>
<td>A provider must only bill for reasonable and necessary medical services. “No payment may be made under Part A or Part B for any expenses incurred for items or services ... which ... are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”</td>
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<td><strong>Item or service is not statutorily excluded from Medicare Coverage</strong></td>
<td>The subject or purpose of a trial must not be statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).</td>
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<td><strong>Item or service is not related to a non covered item/service</strong></td>
<td>Medical and hospital services are sometimes required to treat a condition that arise as a result of services that are not covered because they are determined to be not reasonable and necessary or because they are excluded from coverage for other reasons. Services “related to” noncovered services (e.g., cosmetic surgery, noncovered organ transplants, noncovered artificial organ implants, etc.), including services related to follow-up care and complications of noncovered services which require treatment during a hospital stay in which the noncovered service was performed, are not covered services under Medicare. Services “not related to” noncovered services are covered under Medicare.</td>
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<td><strong>Medicare Coverage for Drugs and Biologicals used On-Label</strong></td>
<td>Medicare generally covers drugs that are approved for inclusion in the following treatises: United States Pharmacopeia National Formulary (SUP-NF), the United States Pharmacopeia-Drug Information (USD-DI), or the American Dental Association (ADA) Guide to Dental Therapeutics, excluding certain drugs unfavorably evaluated in the ADA Guide to Dental Therapeutics. The extent of coverage depends on the part (Part A, Part B, Part D) of the Medicare program that applies to the use of the drug or biological. • Medicare Part A generally covers drugs that are “ordinarily furnished by the hospital for the care and treatment of inpatients”: Use must be “safe and effective” and otherwise “reasonable and necessary.” Drugs approved for marketing by the FDA are considered “safe and effective” when used for indications specified on the labeling. Use of FDA-Approved drug or biological is covered if: o It was injected on or after the date of FDA’s approval; o It is reasonable and necessary for the individuals patient; and o All other applicable coverage requirements are met. • Medicare Part B generally covers drugs that are NOT usually “self-administered,” and that are furnished either (i) by a hospital to an outpatient “incident to” a physician service, or (ii) by a physician (or the physician’s office staff) to a patient “incident to” a physician’s service. • Exceptions to Part B’s “self-administered” coverage restrictions are made for anti-cancer drugs and accompanying anti-emetics, and for immunosuppressive drugs needed by transplant recipients.</td>
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<td><strong>Medicare Coverage for Drugs and Biologicals used OFF-Label</strong></td>
<td><strong>Off label uses of drugs.</strong> Off-label uses of drugs may be covered if the Medicare Contractor determines the use to be medically acceptable taking into consideration major drug compendia, authoritative medical literature and/or accepted local standards of medical practice. • Unlabeled use for anti-cancer. Medicare may cover if the off-labeled drug or regimen of drugs is covered in one of the recognized compendia and not listed as “not indicated” in any of the compendia or if the use is supported by clinical research that appears in peer-reviewed medical literature.</td>
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<td>Medicare Part D Coverage for Drugs and Biologics</td>
<td>• Medicare Part D generally covers drugs that may be dispensed only upon a prescription and that are approved by the FDA or exempted from the FDA approval process</td>
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<td>State Mandated Coverage for Drugs in certain clinical trials</td>
<td>A growing number of states have passed legislation or instituted special agreements requiring health plans to pay the cost of routine medical care received as a participant in a clinical trial. For example: The Michigan Consensus Agreement requires private insurance plans, HMOs and the Michigan Medicaid Program to cover Phase II and III cancer clinical trials that are sponsored or approved by any one of the following: • National Institutes of Health (NIH) • National Cancer Institute • U.S. Food and Drug Administration • U.S. Department of Defense • U.S. Department of Veterans Affairs • Centers for Medicare and Medicaid Services • Centers for Disease Control and Prevention The agreement also covers any side effects from the clinical trial treatment, including hospitalization costs. • Coverage for Phase I trials is under consideration.</td>
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<td>Research Costs—allowable costs</td>
<td>(a) <strong>Principle.</strong> Costs incurred for research purposes, over and above usual patient care, are not includable as allowable costs. (b) <strong>Application.</strong> (1) There are numerous sources of financing for health-related research activities. Funds for this purpose are provided under many Federal programs and by other tax-supported agencies. Also, many foundations, voluntary health agencies, and other private organizations, as well as individuals, sponsor or contribute to the support of medical and related research. Funds available from such sources are generally ample to meet basic medical and hospital research needs. A further consideration is that quality review should be assured as a condition of governmental support for research. Provisions for such review would introduce special difficulties in the Medicare programs. (2) If research is conducted in conjunction with, and as a part of, the care of patients, the costs of usual patient care and studies, analyses, surveys, and related activities to serve the provider’s administrative and program needs are allowable costs in the determination of payment under Medicare.</td>
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| FDA on Devices| Medicare coverage of a device is related to the FDA's determination that the device is “safe and effective”. The FDA determines whether a product is safe and effective as a condition of approval while CMS determines if the device is reasonable and necessary as a condition of coverage for the Medicare population.  
- The Food, Drug and Cosmetic Act requires a manufacturer of medical devices to notify the FDA of its intent to market a medical device. (Premarket Notification “PMN” or 510(k))  
- The FDA determines whether new device is “substantially equivalent” to device marketed prior to passage of Medical Device Amendments of 1976 to Food, Drug & Cosmetic Act.  
  - If FDA determines device is substantially equivalent, it may be marketed immediately and is regulated in the same class as the equivalent device  
  - If not substantially equivalent, clinical testing and premarket approval is required for a new device, unless the device is reclassified into a lower class. Once the studies are completed, the sponsor continues with the PMA application process. A PMA application approved by the FDA permits the applicant to market the device commercially.  
- 3 classes of Medical Devices exist: Class I (General Controls—subject to least regulatory control, e.g. bandages, gloves); Class II (Special Controls—must meet certain performance standards or special controls developed by fed, e.g. powered wheelchairs, infusion pumps), Class III (Pre-Market Approval—including life-supporting, life-sustaining or implantable devices or devices that present potentially unreasonable risk of illness or injury. A Class III device must undergo a pre-market approval process that includes scientific review to ensure the safety and effectiveness of the device)  
- Applicants must support a Pre-market Approval (PMA) application with clinical data demonstrating the safety and effectiveness of the device. FDA may issue an investigational device exemption (IDE) that permits the device to be used in a clinical study in order to develop safety and efficacy data.  
- Clinical investigations of IDE devices must be conducted according to the FDA’s IDE regulations.  
  - Investigational devices subject to IDE regulations are classified as either “significant risk” or “nonsignificant risk”  
  - IDE devices are further classified as either Category A or Category B  
    - Category A (Experimental/Investigational) Novel, “first of kind” experimental investigational devices for which the initial questions of safety and effectiveness of the device have not been proven  
    - Category B (Nonexperimental and/or investigational) devices believed to be in classes I or II or devices believed to be in Class III where the incremental risk is the primary risk in question (i.e., underlying questions of safety and effectiveness have been resolved)  
- Certain clinical investigations of devices (i.e. lawfully marketed devices) are exempt from the IDE regulations                                                                                                                                                                                                                                         | • FDA Overview of Device Regulations  
• US FDA/CDRH: Device Advice - Device Classes  
• 42 CFR Sec. 405.201 [Definition/Categorization of Class I, Class II and Class III devices]  
• FDA IDE Overview  
• 21 CFR sec. 812.3(m) [Definition of Significant Risk Device]  
• 21 CFR sec. 812.36 [Treatment use of an Investigational Device]  
• 21 CFR sec 812.2(c) [Exemption to IDE regs] |
**TOPIC**

**DEFINITION/REQUIREMENT**

**AUTHORITIES**

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**Medicare Coverage of Devices**

- Devices that **may** be covered under Medicare include the following categories:
  - Devices approved by the FDA through the Pre-Market Approval (PMA) process;
  - Devices cleared by the FDA through the 510(k) process;
  - FDA-approved IDE Category B devices; and
  - Hospital Institutional Review Board (IRB) approved IDE devices

- Investigational Devices
  - Category A devices-CMS does not cover Category A devices under Medicare because they do not satisfy the statutory requirement that Medicare pay for devices determined to be reasonable and necessary.
  - Category B devices- CMS may cover Category B devices if they are considered reasonable and necessary and if all other applicable Medicare coverage requirements are met. Local contractor must apply the following criteria when making coverage determinations on FDA-approved IDE Category B devices:
    - The device must be used within the context of the FDA-approved clinical trial;
    - The device must be used according to the clinical trial's approved patient protocols;
    - There may be an established national policy as contained in existing manual instructions, e.g., National Coverage Determinations Manual instructions, etc.;
    - In the absence of national policy, there may be a local policy for similar FDA-approved devices;
    - There may be position papers or recommendations made by national and/or local specialty societies.

- Contractors should also consider, among other factors, whether the device is:
  - Medically necessary for the particular patient and whether the amount, duration, and frequency of use or application of the service are medically appropriate; and
  - Furnished in a setting appropriate to the patient's medical needs and condition.

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**Local Contractor review of clinical trial services**

- Local contractors are directed to “not develop new or revised LMRPs for clinical trial services. Clinical trial services that meet the requirements of the NCD are considered reasonable and necessary.”

- Local contractors must consider whether any restrictions concerning site of service, indications for use, or any other list of conditions for coverage have been placed on a device’s use.

- To the extent that CMS relies on confidential commercial or trade secret information in any judicial proceeding, CMS will maintain confidentiality of the information in accordance with Federal law.

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**Coverage with Evidence Development**

- If the item or service is not considered “reasonable & necessary” under section 1862(a)(1)(A), it may still be considered for coverage under Section 1862(a)(1)(E), which is the basis for CMS’ Coverage with Evidence Development (CED). Section 1862(a)(1)(E) is linked to Section 1142 of the Social Security Act, which allows CMS to work jointly with the Agency for Healthcare Research and Quality (AHRQ) to evaluate and empower CMS to pay for the clinical costs of research. The purpose of CED is to generate data on the utilization and impact of the item or service evaluated in the NCD, so that Medicare can (1) document the appropriateness of use of that item or service in Medicare beneficiaries under current coverage; (2) consider future changes in coverage for the item or service; and (3) generate clinical information that will improve the evidence base on which providers base their recommendations to Medicare beneficiaries regarding the item or service.

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**AUTHORITIES**

- Medicare Benefit Policy Manual, Pub. 100-2, Ch 14, sec. 10 [Coverage of Medical Devices]
- Medicare Benefit Policy Manual, Pub. 100-2, Ch. 14 sec. 20 [FDA Approval Investigational Device Exemptions (IDEs)]
- Medicare Benefit Policy Manual, Pub. 100-2, Ch. 14 sec. 30 [Coverage of FDA approved IDEs]
- SSA 1862(m) [Coverage for routine costs associated with certain clinical trails of Category devices]
- 42 CFR sec 405.201 [Definitions]
- 42 CFR sec. 405.203 [FDA categorization of investigational devices]
- 42 CFR sec. 405.205 [Coverage for Non-experimental/investigational Category B device]
- 42 CFR sec. 405.209 [Payment for Cat B device]
- Medicare Claims Processing Manual, Pub. 100-4, Ch. 32, sec. 69.4 [Local Medical Review Policy]
- 42 CFR sec. 405.211(e) [Procedures for Contractors in making coverage decisions for a non-experimental/investigational (Cat B) device]
- 42 CFR sec. 405.215 [Confidential commercial and trade secret information]
- SSA 1862(a)(1)(E)
- CMS Guidance on Coverage with Evidence Development [including coverage with Clinical study participation (“CSP”)]
- CMS-Coverage with Evidence Development [Includes links to approved CED studies]
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| Waiving Charges for routine care provided in a clinical trial (no evidence of indigency) | If the routine costs of the clinical trial are furnished gratuitously (i.e., without regard to the beneficiary's ability to pay and without expectation of payment from any other source), then Medicare payment cannot be made and the beneficiary cannot be charged. If private insurers deny the routine costs and the provider of services does not pursue the non-Medicare patients for payment after the denials (even though the non-Medicare patient has the ability to pay), Medicare payment cannot be made and the beneficiary cannot be charged for the routine costs. | • MLN Matters #SE0822, September 30, 2008*  
• Medicare Benefit Policy Manual, Pub. 100-2, Ch. 16, sec. 40 [No Legal Obligation to Pay or Provide for Services] |
| Waiving charges for routine care provided in a clinical trial for “indigent” patients | If the routine costs of the clinical trial are not billed to indigent non-Medicare patients because of their inability to pay (but are being billed to all the other patients in the clinical trial who have the financial means to pay even when his/her private insurer denies payment for the routine costs), then a legal obligation to pay exists. Therefore, Medicare payment may be made and the beneficiary (who is not indigent) will be responsible for the applicable Medicare deductible and coinsurance amounts. | • MLN Matters #SE0822, September 30, 2008*  
• Medicare Benefit Policy Manual, Pub. 100-2, Ch. 16, sec. 40 [No Legal Obligation to Pay or Provide for Services]  
• OIG Advisory Opinion 08-11 [Lott Study]  
• OIG Advisory Opinion 04-01 [BARI 2D Study]  
• OIG Advisory Opinion 02-16 [ACCORD Study]  
• OIG Advisory Opinion 00-5 [NETT Study] |
| Waiving charges for co-pays related to clinical trial items or services | If a research sponsor offers to pay cost-sharing amounts owed by the beneficiary (such as co-pays), this could be a fraud and abuse problem [particularly for industry sponsored studies] | • MLN Matters #SE0822, September 30, 2008*  
• Medicare Benefit Policy Manual, Pub. 100-2, Ch. 16, sec. 40 [No Legal Obligation to Pay or Provide for Services]  
• OIG Advisory Opinion 08-11 [Lott Study]  
• OIG Advisory Opinion 04-01 [BARI 2D Study]  
• OIG Advisory Opinion 02-16 [ACCORD Study]  
• OIG Advisory Opinion 00-5 [NETT Study] |
| Setting Charges for an Investigational Drug | (d) Charging for and commercialization of investigational drugs –  
• (1) Clinical trials under an IND. Charging for an investigational drug in a clinical trial under an IND is not permitted without the prior written approval of FDA. In requesting such approval, the sponsor shall provide a full written explanation of why charging is necessary in order for the sponsor to undertake or continue the clinical trial, e.g., why distribution of the drug to test subjects should not be considered part of the normal cost of doing business.  
• (2) Treatment protocol or treatment IND. A sponsor or investigator may charge for an investigational drug for a treatment use under a treatment protocol or treatment IND provided: (i) There is adequate enrollment in the ongoing clinical investigations under the authorized IND; (ii) charging does not constitute commercial marketing of a new drug for which a marketing application has not been approved; (iii) the drug is not being commercially promoted or advertised; and (iv) the sponsor of the drug is actively pursuing marketing approval with due diligence. FDA must be notified in writing in advance of commencing any such charges, in an information amendment submitted under 312.31. Authorization for charging goes into effect automatically 30 days after receipt by FDA of the information amendment, unless the sponsor is notified to the contrary.  
• (3) Noncommercialization of investigational drug. Under this section, the sponsor may not commercialize an investigational drug by charging a price larger than that necessary to recover costs of manufacture, research, development, and handling of the investigational drug.  
• (4) Withdrawal of authorization. Authorization to charge for an investigational drug under this section may be withdrawn by FDA if the agency finds that the conditions underlying the authorization are no longer satisfied. | • 21 CFR 312.7 [Promotion and charging for investigational new drugs] |
| Setting charges for an Investigational Device | A sponsor, investigator, or any person acting for or on behalf of a sponsor or investigator shall not:  
* * *  
(b) Commercialize an investigational device by charging the subjects or investigators for a device a price larger than that necessary to recover costs of manufacture, research, development, and handling. | • 21 CFR sec. B12.7 [Prohibition of Promotion and other practices] |
### No-Cost Items

- Providers cannot bill Medicare for items provided free of charge by the sponsor.
- In most cases, institutional providers (hospitals) are required to bill a no cost item due to system edits that will ensure that an item (received at no cost or not) is billed along with an associated service (e.g., a device/drug must be reported along with an implantation/administration). To report a no cost item, institutional providers must place a token charge in the “Non-Covered” charge field for the no cost item.
- Outpatient hospitals billing “no cost” devices must append the `-FB` modifier to the procedure code for implanting the “no cost” device, along with the appropriate condition code (in Table 1 above—**BUT NOTE**—no code applicable to research). The modifier will identify the procedure code line for the “no cost” device, while the condition code will explain the reason why the device was provided free of cost.

#### Authorities
- SSA sec 1862(a)(2)
- Medicare Claims Processing Manual, Ch. 32, sec. 67 [No Cost Items]

### Placing Sponsor Covered Charges on the Claim Form

- Practitioners [physician] providers should not bill for no cost items as there is no “Non-Covered” charges field on the claims and there are also no [CMS] system edits in place to require providers to do so.
- Items and services provided free of charge by research sponsors may not be billed to be paid by Medicare, and providers are **not** required to submit the charge to Medicare. If it is necessary for a provider to show the items and services that are provided free of charge in order to receive payment for the covered routine costs (e.g., administration of a non-covered chemotherapeutic agent), providers are instructed to submit such charges as “non-covered” at the time of entry, while also assuring that the beneficiary is not held liable for the no cost items.

#### Authorities
- Medicare Claims Processing Manual, Pub. 100-4, Ch. 32, sec. 67.1 and 67.2 [Practitioner and Institutional billing for No Cost Items]

## Documentation and Claim Requirements

### CRB Medical Record Documentation Requirements

The billing provider must include in the beneficiary’s medical record the following information: trial name, sponsor, and sponsor-assigned protocol number. This information does not need to be submitted with the claim but must be provided if requested for medical review.

#### Authorities
- July 9, 2007 National Coverage Decision Routine Costs in Clinical Trials (“CTP”)
- Medicare National Coverage Determinations Manual, Pub. 100-03, Ch. 1, Part 4, sec. 310 [Clinical Trials]
- Medicare Claims Processing Manual, Pub. 100-4, Ch. 32, sec. 69.3 [Medical Records Documentation Requirements]

### Separate Line Items

Physicians and hospitals should enter clinical trial and non-clinical trial services on separate line items when billing both types of services on the same claim.

#### Authorities
- Medicare Claims Processing Manual, Pub. 100-4, Ch. 32, sec. 69.5 [Billing Requirements General]

### General Routine Care Claim Requirements Practitioners & Suppliers

- For Qualified studies:
  - V70.7 [Examination of participant in clinical trial] is required as the **primary** diagnosis if healthy control. If subject is not a healthy control place the V70.7 as the **secondary** diagnosis and the service will be processed as “a therapeutic clinical trial service.”
  - Modifier Q1

#### Authorities
- July 9, 2007 National Coverage Decision Routine Costs in Clinical Trials (“CTP”)
- Medicare National Coverage Determinations Manual, Pub. 100-03, Ch. 1, Part 4, sec. 310 [Clinical Trials]
- Medicare Claims Processing Manual, Pub. 100-4, Ch. 32, sec. 69.6 [Billing Requirements for Clinical Trials]
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| General Routine Care Claim Requirements Institutional Providers | For Qualified studies:  
• Condition code 30 (qualifying clinical trial) is reported at the claim level  
• Modifier ‘Q1’ (only for institutional outpatient claims)  
• V70.7 [Examination of participant in clinical trial] is required as the secondary diagnosis. | • July 9, 2007 National Coverage Decision Routine Costs in Clinical Trials (“CTP”)  
• Medicare Claims Processing Manual, Pub. 100-4, Ch. 32, sec. 69.6 [Billing Requirements for Clinical Trials] |
| V70.7 | Means “examination of participant in clinical trial”  
“do not submit claims with diagnosis code V70.7, unless there are covered charges, and they represent routine patient care” | • Medicare Claims Processing Manual, Pub. 100-4, Ch. 32, sec. 69.6 [Billing Requirements for Clinical Trials]  
• A14637 Riverbend Article, Billing for Clinical Trials and IDEs (Oct. 10, 2003) |
| Modifier Q0 | Cat A or Cat B devices. Practitioner/suppliers must bill a Q0 modifier (“Investigational clinical service provided in a clinical research study that is in an approved clinical research study”) along with the IDE number.  
“The use of this [Q0] modifier indicates that the provider is certifying FDA approval of a clinical trial for the device.” | • Transmittal 1418 (CR 5805) Jan. 18, 2008  
• Medicare Claims Processing Manual, Pub. 100-4, Ch. 32, secs. 68.3 [Cat A], 68.4 [Cat B], 69.6 [Billing Requirements for Clinical Trials]  
• ML Matters #MM5805 (Jan 18, 2008) [New Healthcare Common Procedure Coding System (HCPCS) Modifiers when Billing for Patient Care in Clinical Research Studies] |
| Modifier Q1 | Modifier Q1 [“Routine clinical service provided in a clinical research study that is in an approved clinical research study”] is line item specific and must be used to identify items and services that constitute [1] medically necessary routine patient care or [2] treatment of complications arising from a Medicare beneficiary’s participation in a Medicare covered clinical trial. When billed in conjunction with the V70.7 diagnosis code, the Q1 modifier will serve as the provider’s attestation that the service meets the Medicare coverage criteria (i.e., was furnished to a beneficiary who is participating in a Medicare qualifying clinical trial and represents routine patient care, including complications associated with qualifying trial participation). | • Transmittal 1418 (CR 5805) Jan. 18, 2008  
• Medicare Claims Processing Manual, Pub. 100-4, Ch. 32, secs. 68.3 [Cat A], 68.4 [Cat B], 69.6 [Billing Requirements for Clinical Trials]  
• ML Matters #MM5805 (Jan 18, 2008) [New Healthcare Common Procedure Coding System (HCPCS) Modifiers when Billing for Patient Care in Clinical Research Studies] |
| Condition Code 30 | Requirement for institutional providers (only) to use Condition Code 30 on a claim level for qualified clinical trials | • Medicare Claims Processing Manual, Pub. 100-4, Ch. 32, sec. 69.6 [Billing Requirements for Clinical Trials] |
| See also Revenue Code 624 and IDE # in Device section below | [see Investigational Device Section Below] |
| 8-digit Registry Number | Not currently required, however, effective for clinical trial claims received after April 1, 2008, (regardless of date of service) providers can begin to report an 8 digit clinical trial number | • MLN Matters #5790 (April 7, 2008) CR5790, Related CR Transmittal R100TN  
• CMS Transmittal 310 (CR 5790) Jan 18, 2008  
• Medicare Claims Processing Manual, Pub. 100-4, Ch. 32, sec. 69.6 [Billing Requirements for Clinical Trials] |
| Medicare Advantage | Covered clinical trial services furnished to beneficiaries enrolled in managed care plans shall be paid in accordance with applicable fee for services rules | • Medicare Claims Processing Manual, Pub. 100-4, Ch. 32, sec. 69.9 [Processing Fee For Service Claims for Covered Clinical Trial Services Furnished to Managed Care Enrollees] |
### Investigational Devices

#### Writing to Contractors for Approval of IDE studies

Providers that participate in an IDE trial and anticipate filing Medicare claims must notify the Medicare contractor **prior to a submission of a claim for payment**. Providers shall notify their contractor of the Category A IDE device trial before billing routine costs of clinical trials involving a Category A device, as listed in Section 68.2 above.

#### IDE Study materials required by Contractors (Example from Part A, National Government Services)

Electronic submission of:
- A **non-redacted** copy of the FDA-approval letter provided to the sponsor or manufacturer of the device. The approved IDE code number must be on the letter.
- **[per 68.2, name of the device [both trade, common or usual, and classification name]]**
- A copy of the IRB-approved protocol **[or, per 68.2, a brief summary of the study design]**.
- A description of any action(s) taken to conform to any applicable IDE special controls.
- A narrative description of the device sufficient to make a payment determination.
- A statement indicating how the device is similar to and/or different from other comparable products.
- The protocol for obtaining informed consent from the beneficiary(ies) participating in the trial.
- Description of any items or services for which the providers (hospital / physicians) are being reimbursed by the sponsor.
- Copies of **at least two supporting scientific articles** (full texts) for the investigational device and its intended indication published in peer reviewed literature are also required.
- **[per 68.2, an indication of whether the device will be billed on an inpatient or outpatient claim]**

#### Specific Cat A device Study Requirements

Cat A device must be intended for diagnosis monitoring or treatment of “immediately life-threatening disease/condition.” Upon receiving the required information for the trial, the contractor will determine if the Category A device, as used in the trial, is intended for the diagnosis, monitoring, or treatment of an immediately life-threatening disease/condition. If the contractor determines that the device does, in fact, meet the requirements of coverage, then the provider may begin billing the routine costs of a clinical trial involving a Category A device. (so long as study is initiated prior to January 1, 2010)

In addition to billing the routine costs, providers must identify the line for which the Category A IDE device is being billed.

#### Revenue Code 624

**Cat A**: Institutional providers must “bill” Cat A device involved in a clinical trial by placing the Cat. A IDE Number on a 0624 (IDE) revenue code line, with the charges for the device placed in the “Non-covered” charges field.

**Cat B**: Institutional providers must bill the Category B IDE Number on a 0624 revenue code line with charges in the covered charges field (providers receiving the device free of charge must bill the IDE charges as non-covered).
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<td><strong>IDE #</strong></td>
<td>As a requirement for Category B IDE coverage, providers must bill a six-digit IDE Number that begins with a “G” (i.e., G123456). Physicians billing electronically must place the IDE number on the 2300 Investigational Device Exemption Number REF segment, data element REF02 (REF01=LX) of the 837p claim format. If billing on the CMS-1500 paper form, the IDE number must be on Item 23. Hospitals billing electronically must place the IDE number on 2300 Investigational Device Exemption Number REF Segment, data element REF02 (REF01=LX) of the 837i claim format. If billing on the CMS-1450 paper form, the IDE number must be in Form Locator 43.</td>
<td>• Medicare Claims Processing Manual, Pub. 100-4, Ch. 32, secs. 68.3, 68.4. &amp; 160.1 [Billing Requirements for Providers Billing Routine Costs of Clinical Trials Involving a Category A, Category B IDE, or Category B PTA study] • CMA FAQ No 5142 “What are the billing instructions for costs covered by clinical trials involving Investigational Device Exemption (IDE) Category A devices?” (Updated 8/29/08)</td>
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<td><strong>PMA #</strong></td>
<td>Currently, in order to receive reimbursement for procedures performed as part of a carotid artery stenting post-approval study, providers must include the FDA-issued PMA number on each claim to indicate participation in a specific study. Billing Post Approval Studies is similar to normal Category B IDEs billing procedures, except that under Post Approval coverage, providers must bill the Pre-Market Approval (PMA) number assigned by the stent system by the FDA. PMA numbers are like typical IDE Numbers in that they have six digits, but they begin with a “P” (i.e., P123456) instead of “G.”</td>
<td>• Medicare Claims Processing Manual, Pub. 100-4, Ch. 32, secs. 68.3, 68.4. &amp; 160.1 [Post-approval study coverage]</td>
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| **NON-QUALIFIED STUDIES** | CMS re: what to do with items and services in Non-Qualified studies | CMS Final Decision for Clinical Trial Policy - Q&As (Oct. 17, 2007) |

| CMS Q4: How does CMS address the perception among the public and some Medicare contractors that privately funded studies were not subject to the deeming process established by the 2000 policy? | Q4: We understand that the current clinical trial policy has led to some confusion on this point. Trials that do not meet the existing criteria for deemed trials should contact their local Medicare contractors to determine whether items and services will be covered in that geographic area. |

| **STUDY REGISTRATION** | **Registration Requirements** | FDAAA (Public Law 110-85) |

<p>| The Food and Drug Administration Modernization Act (FDAMA) of 1997 resulted in the establishment of ClinicalTrials.gov and mandated registration of FDA-regulated efficacy drug trials for serious or life-threatening diseases and conditions. | • Since 2005, many, if not most, medical journals began to require prospective public registration of certain clinical trials as a prerequisite for publication. Included among them, for example are the International Committee of Medical Journal Editors (ICMJE) member journals, including JAMA &amp; New England Journal of Medicine. |
| Since 2005, many, if not most, medical journals began to require prospective public registration of certain clinical trials as a prerequisite for publication. Included among them, for example are the International Committee of Medical Journal Editors (ICMJE) member journals, including JAMA &amp; New England Journal of Medicine. | • The Food and Drug Administration Amendments Act (FDAAA) of 2007 expanded the scope of clinical trials that must be registered, requires registration information that was previously optional, adds a few additional registration data elements, requires eventual inclusion of trial results information, and provides penalties for noncompliance. |</p>
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| **Registration of Which Studies?** | Collectively, the FDAMA, FDAAA, and ICMJE requirements cover the following types of studies:  
- Controlled clinical investigations of drugs and biologics subject to FDA regulation, other than Phase I trials.  
- Controlled trials with health outcomes of devices subject to FDA regulation (other than small feasibility studies) and pediatric postmarket surveillance.  
- Any research project that prospectively assigns human subjects to intervention and concurrent control or comparison groups in order to study the cause-and-effect relationship between a medical intervention and a health outcome.  
- Clinically directive trials - those that test a clinical hypothesis about health outcomes, including all trials whose primary purpose is to affect clinical practice. Some journals have additional specifications for which studies must be registered. For example, JAMA requires registration of all randomized clinical trials (RCTs), except for Phase I trials, that “randomize” human research participants to an intervention. | NOT-OD-08-023: Clinical Trials Registration in ClinicalTrials.gov (Public Law 110-85): Competing Applications and Non-Competing Progress Reports |
| **Registration of Studies by when?** | For ICMJE publication:  
- **Before** beginning subject enrollment*  
- Note: The ICMJE requirement is more stringent than the FDAAA requirement (below) for timing of registration relative to patient/subject enrollment.  
For FDAAA compliance:  
- **December 26, 2007** or 21 days after the first patient is enrolled* -- for trials initiated after 9/27/2007, or trials that are ongoing as of 12/26/2007  
- **September 27, 2008** - for trials that were ongoing as of 9/27/2007 and do **not** involve a “serious or life-threatening disease or condition”  
- **Exception** - Trials that (1) were ongoing as of 9/27/2007, (2) **do** involve a “serious or life-threatening disease or condition”, and (3) are completed by 12/26/2007, are not subject to the FDAAA requirements, but are likely to be subject to the pre-existing FDAMA registration requirements. For purposes of this exception, the “completion date” is the date the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome. | NOT-OD-08-023: Clinical Trials Registration in ClinicalTrials.gov (Public Law 110-85): Competing Applications and Non-Competing Progress Reports |
| **Registration of Studies by Whom?** | Sponsored clinical trials are likely to be registered on ClinicalTrials.gov by the lead sponsor (the clinical trial agreement negotiated through DRDA may specify who is responsible). Clinical trials conducted under an FDA IND or IDE are likely to be registered by the IND or IDE holder. Otherwise, trial registration falls to the study investigator. Before investigators register a sponsored trial, they should search the ClinicalTrials.gov website to be sure that the trial has not already been registered. | • ClinicalTrials.gov  
• ClinicalTrials.gov Protocol Registration System Info |

**GENERAL OBLIGATIONS & PROHIBITIONS**

**Medicare Secondary Payor**  
Medicare Secondary Payor laws prohibit Medicare payment (excluding conditional payments) for an item/service where payment “has been made, or can reasonably be expected to be made under . . . [a primary plan] liability insurance policy or plan (including a self-insured plan) . . .”

- 42 USC sec. 1395y(b)(2)(A) [Medicare Secondary Payor]  
- 42 CFR sec. 411.20(a)
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<td>Prohibition on making false statements or misrepresentations of material facts concerning requests for payment under Medicare</td>
<td>A provider shall not knowingly or with “deliberate ignorance” or “reckless disregard” make false statements or misrepresentations of material facts concerning requests for payment under Medicare</td>
<td>[42 USC sec. 1320a-7b(a)] [making or causing to be made false statements]</td>
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<td>Prohibition on making false statement or misrepresentation of material facts concerning requests for payment under [Michigan] Medicaid</td>
<td>[Most states now have Medicaid false claims statutes with obligations and penalties at least as strong as the federal false claims statute] (1) A person shall not make or present or cause to be made or presented to an employee or officer of this state a claim under the social welfare act, Act No. 280 of the Public Acts of 1939, as amended, being sections 400.1 to 400.121 of the Michigan Compiled Laws, upon or against the state, knowing the claim to be false. (2) A person shall not make or present or cause to be made or presented a claim under the social welfare act, Act No. 280 of the Public Acts of 1939, which he or she knows falsely represents that the goods or services for which the claim is made were medically necessary in accordance with professionally accepted standards. Each claim violating this subsection shall constitute a separate offense. A health facility or agency shall not be liable under this subsection unless the health facility or agency, pursuant to a conspiracy, combination, or collusion with a physician or other provider, falsely represents the medical necessity of the particular goods or services for which the claim was made. (3) A person who violates this section is guilty of a felony, punishable by imprisonment for not more than 4 years, or by a fine of not more than $50,000.00, or both.</td>
<td>[MCL 400.607] [MI Medicaid False Claims Act]</td>
</tr>
<tr>
<td>State all payor false claims Statutes</td>
<td>Many states have statutes prohibiting false claims for all payors (1) A person shall not make or present or cause to be made or presented to a health care corporation or health care insurer a claim for payment of health care benefits knowing the claim to be false. (2) A person shall not make or present or cause to be made or presented to a health care corporation or health care insurer a claim for payment of health care benefits which he or she knows falsely represents that the goods or services were medically necessary in accordance with professionally accepted standards. Each claim which violates this subsection shall constitute a separate offense. A health facility or agency shall not be liable under this subsection unless the health facility or agency, pursuant to a conspiracy, combination, or collusion with a physician or other provider, falsely represents the medical necessity of the particular goods or services for which the claim was made. (3) A person shall not knowingly make or cause to be made a false statement or false representation of a material fact to a health care corporation or health care insurer for use in determining rights to health care benefits. Each claim which violates this subsection shall constitute a separate violation.</td>
<td>[MCL 752.1003] [MI Health care False Claims Act]</td>
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<tr>
<td>Prohibition on knowingly and willfully soliciting or receiving or offering or paying remuneration in exchange for referrals/generation of federal healthcare business</td>
<td>A person shall not knowingly or willfully offer or pay any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person— (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program</td>
<td>[SSA sec. 1128B(b)] [42 USC sec. 1320a-7(b)] [Illegal remuneration] [see also list of advisory opinions under prohibition on inducing Medicare/Medicaid beneficiaries.]</td>
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| **Prohibition on Billing**  
No Cost Items | Providers are not to seek reimbursement from Medicare for no cost items  
On occasion, providers may receive an item (such as a device or drug) that is offered by a manufacturer/supplier free of charge. Such items, for purposes of these instructions, are considered “no cost items.” Providers are not to seek reimbursement for no cost items as noted in Section 1862(a)(2) of the Social Security Act. | • SSA sec. 1862(a)(2) [No legal obligation to pay]  
• Medicare Claims Processing Manual, Ch. 32, sec. 67 [No Cost Items] |
| **Prohibition on Double Billing.** | A hospital or physician may not bill Medicare and simultaneously bill a liability insurer (or assert or maintain a lien against the beneficiary’s liability insurance settlement) (or another source of payment, such as a sponsor Sample CMS references to “double billing”  
• Cases without medical need for replacement would be considered double billing.  
• Collecting from a beneficiary (or other source such as sponsor) where full payment is made on a bundled basis would constitute double billing. | • CMS Transmittal 332 Oct. 22, 2004 [Policy and Refinements on Billing Noncovered Charges to the FI]  
• Medicare Claims Processing Manual, Pub. 100-04, Ch. 1, Sec. 60.4.6 [Clarification on notice requirements related to billing “bundled” non-covered institutional benefits]  
• MLMatters #SAE0424 [Clarification on Billing LVADs] |
| **Prohibition on inducing Medicare or Medicaid Beneficiaries** | In the absence of financial need, offering a Medicare or Medicaid beneficiary “remuneration” may violate the “beneficiary inducement statute” where the person offering the remuneration knows or should know that the remuneration is “likely to influence” the beneficiary to order or receive items or services from a particular provider. Remuneration includes waiver of cost sharing obligations  
• SSA sec. 1128A(a)(5) 42 USC 1320a-7a  
• OIG Advisory Opinion 05-02 [BARI 2D Study]  
• OIG Advisory Opinion 00-05 [NETT Study] | • SSA sec. 1128A(a)(5) 42 USC 1320a-7a  
• OIG Advisory Opinion 08-11 [Lott Study]  
• OIG Advisory Opinion 04-01 [BARI 2D Study]  
• OIG Advisory Opinion 02-16 [ACCORD Study]  
• OIG Advisory Opinion 00-5 [NETT Study] |
| **Hospital Obligation for Ethical Billing** | Hospital providers are required to follow “ethical behavior” in their care treatment, and services and business practices. Hospital providers are to provide patients with information about charges for which they will be responsible | • Joint Commission standard RI.1.10, element of performance 5 |

**GENERAL RESEARCH AUTHORITIES**

| Protection of Human Subjects | 21 CFR Sec. 50 [Protection of Human Subjects] |
| Financial Disclosure by Clinical Investigators | 21 CFR Sec. 54 [Financial Disclosure by Clinical Investigators] |
| Institutional Review Boards | 21 CFR Sec. 56 [Institutional Review Boards] |
| Prohibitions related to Investigational devices | 21 CFR sec. 812.7 [Prohibition of Promotion and other practices] |

A sponsor, investigator, or any person acting for or on behalf of a sponsor or investigator shall not:  
(a) Promote or test market an investigational device, until after FDA has approved the device for commercial distribution.  
(b) Commercialize an investigational device by charging the subjects or investigators for a device a price larger than that necessary to recover costs of manufacture, research, development, and handling.  
(c) Unduly prolong an investigation.  
If data developed by the investigation indicate in the case of a class III device that premarket approval cannot be justified or in the case of a class II device that it will not comply with an applicable performance standard or an amendment to that standard, the sponsor shall promptly terminate the investigation.  
(d) Represent that an investigational device is safe or effective for the purposes for which it is being investigated.