INNOVATORS' GUIDE TO NAVIGATING CMS

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OVERVIEW

With a Medicare budget of approximately $450 billion and serving over 45 million beneficiaries, the Centers for Medicare & Medicaid Services (CMS) plays a key role in the overall direction of the health care system. From the beginning of the Medicare program, one of the most important program goals for CMS has been to make "the best of modern medicine" available to Medicare beneficiaries. Over the last 40 years, significant advances in medical science have offered improved health for beneficiaries and others. Many of these advances have involved the use of new technologies, such as prescription drugs and medical devices.

CMS, through its Council on Technology and Innovation (CTI), has developed the Innovators' Guide to Navigating CMS to assist stakeholders in understanding the processes used to determine coverage, coding, and payment for new technologies under the Medicare fee-for-service program. This guide is only intended as a general summary. The information provided is not intended to grant rights or impose obligations. While a chapter may contain references or links to statutes, regulations, or other policy materials, it is not intended to take the place of applicable statutory law or regulations. We encourage readers to review the specific statutes, regulations, and other interpretive materials for a full and accurate statement of their contents.

In recent years, CMS has made substantial progress in defining the coverage, coding, and payment processes and how they relate to each other. In order to improve stakeholder understanding and consider how these processes might be further improved, CMS has made the requirements of these processes, including how decisions are made more transparent and provided opportunities for public input to facilitate dialogue between CMS and interested stakeholders. This better enables stakeholders to develop a strategy for working with CMS to support timely introduction of innovative technology to the Medicare marketplace, allowing Medicare beneficiaries timely access to advances in health care.

Payment for many technological advances can be made under one of Medicare's payment methodologies without being preceded by an explicit coverage determination, coding change, and/or payment decision by CMS. However, the Agency will specifically evaluate issues involving coverage, coding, and/or payment with respect to certain technological advances. The basic analytical framework that CMS uses for each of these issues is as follows:

1) **Coverage**

Medicare's authority to cover or exclude certain items or services is governed by the Social Security Act (the Act) and implementing regulations.

- *Benefit Category* – Does the new technology fall into at least one defined benefit category or categories under the Act?

- *Statutory Exclusion* – Does the new technology involve an item or service that is specifically excluded by the Act?
- *Reasonable and Necessary* **–** Is the new technology "reasonable and necessary" for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member?

2) **Coding**
   - *Clinically Different* **–** Are changes in coding needed to accommodate the new technology? In most cases, new items and services are adequately described in existing codes. However, some new technologies may warrant differentiation through the creation of new codes.

3) **Payment**
   - *Payment System* **–** Which fee-for-service payment system(s) does the new technology fit into (e.g., hospital inpatient prospective payment system, physician fee schedule)?
   - *Payment Amount* **–** If the new technology warrants a new code, how will the payment amount be determined?

Coverage

CMS and its administrative contractors (MACs, FIs, and carriers) have the authority to develop coverage determinations for particular items or services or to decide claims on a case-by-case basis. The Agency may choose to develop a national coverage policy to ensure that similar claims will be adjudicated under uniform criteria. Coverage policies are more likely to be developed when the item or service produces significant clinical consequences for beneficiaries, the medical community is divided about the merits of an item or service for a particular population, or when the item or service has a significant impact on the Medicare program.

A Medicare contractor develops Local Coverage Determinations (LCDs) that apply only within the jurisdiction served by the individual contractor. Administrative Law Judges (ALJs) must give substantial deference to LCDs. CMS makes National Coverage Determinations (NCDs) that are binding policies for all Medicare contractors, ALJs and the Medicare Appeals Council.

Coding

Currently, CMS uses the International Classification of Diseases, 9th Edition, Clinical Modification (ICD-9-CM) and the Healthcare Common Procedure Coding System (HCPCS) for processing Medicare claims. In contrast to coverage decisions, changes to coding systems are made strictly at the national level. Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), contractors can no longer establish local codes, although new technologies are sometimes accommodated by 'not otherwise classified' codes pending determination of a new code assignment. In many instances new technologies are adequately described by existing codes.

Payment

Payment levels for most of Medicare's fee-for-service payment systems are structured to gradually adjust to the use of a new technology, and in general do not require major modifications. For example, many institutional payment systems calculate payments based on claims and other data. As a new technology is used to treat Medicare beneficiaries, its relative use will be reflected in payment for the service using the technology. In certain cases, payment adjustments for new technologies are appropriate. Medicare's inpatient and outpatient prospective payment systems include provisions designed to provide an extra payment amount for certain new technologies. To merit such additional payment, the new technology generally must represent a substantial clinical improvement relative to existing technologies and meet specific cost thresholds. However, for payment under the outpatient prospective payment system, a service may be assigned to a New Technology Ambulatory Payment Classification (APC) group without demonstrating substantial clinical improvement.

Timing of Policy Decisions

Coverage, coding, and payment decisions are not necessarily made in any particular order. For example, a manufacturer may have secured a new code before seeking Medicare coverage. In addition, while CMS will not generally accept a coverage determination request for a device or pharmaceutical that is not approved or cleared for marketing by the Food and Drug Administration (FDA), applicants may apply for a new technology hospital inpatient add-on payment several months prior to the technology's receipt of FDA approval, as long as FDA approval is granted before CMS makes its decisions for the inpatient prospective payment system (IPPS) final rule. Because CMS may add new services or pass-through items for payment on a quarterly basis under the hospital outpatient prospective payment system (OPPS), lead time prior to FDA approval is not needed or allowed for OPPS applications for New Technology APCs or pass-through drugs, biologicals, or devices.

Timelines for Medicare coding, coverage and payment decisions may often span a 12 month period. A manufacturer should be cognizant of these different timeframes in order to navigate a technology's adoption through the Medicare program. Local and national coverage decisions are made under specific timeframes to accommodate public notice and comment requirements. Coding changes are commonly made on an annual basis, while some payment changes may occur quarterly. For planning purposes, this guide contains a set of charts that provide key milestones for coverage, coding, and payment decision-making processes including the many opportunities for public input.

CMS Relevant Components

In addition to understanding the various milestones, it is helpful to know which CMS components to contact regarding Medicare decisions for new technologies under the coverage, coding and payment processes. Each component's responsibilities are described below.

Office of Clinical Standards and Quality

The Office of Clinical Standards and Quality (OCSQ) oversees national quality initiatives and includes the Coverage and Analysis Group (CAG), which is responsible for developing national coverage policy. CAG also provides oversight of Medicare contractors to ensure that the local coverage determination (LCD) process is properly followed. Within CAG, coverage determinations about drugs, non-implantable devices, and laboratory and diagnostic tests are referred to the Division for Items and Devices. Other coverage topics, including surgical procedures and implantable devices, are referred to the Division of Medical and Surgical Services. The Division of Operations and Information Management provides ongoing scanning of industry developments to keep CAG staff abreast of new and developing treatments and technologies that may result in national coverage issues and maintains liaisons with other Department components, such as the FDA. This division is also responsible for oversight of the Medicare Evidence Development & Coverage Advisory Committee (MedCAC) and public notice and comment processes.

Center for Medicare Management

The Center for Medicare Management (CMM) develops payment rules and decisions, undertakes benefit category determinations, and formulates Medicare policy for the development and maintenance of new and revised codes. Within CMM, the Hospital and Ambulatory Policy Group (HAPG) is responsible for refining hospital and most outpatient payment systems. This group contains four Divisions:

- The Division of Acute Care defines the scope of Medicare benefits for services provided by hospitals to inpatients, and develops, updates, and evaluates the hospital inpatient prospective payment system (IPPS) for payments to hospitals for inpatient services and associated capital costs. This Division considers applications for temporary supplemental payments for new technologies under the IPPS. It also develops and maintains new and revised codes for the ICD-9-CM coding system used for inpatient hospital services.

- The Division of Ambulatory Services formulates payment policies for ambulance services, rural health clinics, clinical laboratory services, blood, blood products, and hemophilia clotting factors. This Division also develops payment policies for drugs provided under Medicare Part B including those drugs provided by physicians (e.g., injectable drugs, vaccines, chemotherapy agents), and drugs used in connection with

durable medical equipment.

- The Division of Outpatient Care develops and maintains the hospital outpatient prospective payment system (OPPS) and the ambulatory surgical center (ASC) payment system. This Division considers applications for temporary supplemental payments for new technologies and new drugs, biologicals, and radiopharmaceuticals used within a hospital outpatient department that are payable under the OPPS and may be payable under the ASC payment system and payment adjustments for new technology intraocular lenses provided in ASCs. This Division also staffs biannual meetings of the Advisory Panel on Ambulatory Payment Classification (APC) Groups whose purpose is to advise the Secretary of the Department of Health and Human Services and the Administrator of CMS about the clinical integrity of the APC groups and their associated weights.

- The Division of Practitioner Services develops, updates, and evaluates payment policies and systems for physicians and non-physician practitioners. As part of these responsibilities, the Division develops payment amounts for all services paid under the Medicare physician fee schedule. This fee schedule is used to pay physicians and many other non-physician practitioners (i.e., nurse practitioners, physician assistants, psychologists, social workers, physical and occupational therapists, audiologists and others) for their services to Medicare beneficiaries. This fee schedule is based on the establishment of relative values for physician work, practice expense, and professional liability for each service. This Division also coordinates with the American Medical Association (AMA) through the Relative Value Update Committee (RUC) that makes recommendations to the Secretary regarding the relative value units (RVUs) that form the basis of Medicare payment for physician services.

Another group within CMM, the Chronic Care Policy Group (CCPG), develops and maintains payment systems for post-acute care services (e.g. inpatient rehabilitation facilities, inpatient psychiatric facilities, skilled nursing facilities, home health agencies, and hospice care), renal dialysis, and durable medical equipment used outside of hospital outpatient departments and ambulatory surgical centers. This group contains six Divisions:

- The Division of Home Health, Hospice, and HCPCS maintains and updates level II of the Healthcare Common Procedure Coding System (HCPCS) code set. The Level II HCPCS is a national standard code set adopted by HIPAA for use by all payers (Medicare, Medicaid, and private insurers) and used primarily to identify products, supplies, and services not included in the CPT-4[1] codes. This division also develops and evaluates Medicare policies and standards on payment for the home health and hospice programs.

- The Division of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy develops and evaluates Medicare policies and standards on payment methods for items and services furnished by DMEPOS suppliers and the

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scope of benefits for DMEPOS. In addition, the division is responsible for developing, implementing, and maintaining national payment and operational policies for the Medicare DMEPOS competitive bidding program.

- The Division of Institutional Post-Acute Care develops and evaluates Medicare policies and standards on payment methods for services provided by skilled nursing facilities and inpatient rehabilitation facilities and the scope of benefits for both programs.

- The Division of Chronic Care Management develops, evaluates, and reviews purchasing policies, regulations and instructions concerning services for renal dialysis, partial hospitalization at community mental health centers and hospitals, religious non-medical healthcare institutions, and the program of all-inclusive care for the elderly. In addition, this division develops and evaluates Medicare policies and standards on payment methods for services provided by inpatient psychiatric facilities.

- The Division of Technical Payment Policy develops, updates, and evaluates policies designed to improve the functioning of the Medicare program, engages in activities that promote the efficiency and quality of services delivered by providers, and works on initiatives to facilitate beneficiary access to care. This division also develops policies concerning assignment and reassignment of benefits, mandatory claims submission, limiting charge, beneficiary signatures on claims, timely filing, and appeals before the Provider Reimbursement Review Board. Finally, the Division is responsible for certain policies concerning reimbursement for costs claimed by organ procurement organizations (OPOs) and hospital-OPO designated service area waiver requests.

- The Division of Cost Reporting develops and evaluates national policies, regulations, and instructions for payment/reimbursement of the costs incurred by providers of services and other classes of facilities under the Medicare program. This division also develops policies pertaining to the use of all cost reporting forms, schedules, and related instructions necessary for paying health care institutions.

Office of Financial Management

The Program Integrity (PI) Group, within the Office of Financial Management, is responsible for utilization management and providing national instructions and directions to the Medicare contractors that are responsible for performing these functions. Although exact numbers vary from year-to-year, at the time of publication of this report, these included fiscal intermediaries (FIs), which mostly process and review Part A claims; carriers, which process and review Part B claims; MACs[2], which process Part A, Part B,

[2] Historically, fiscal intermediaries and carriers contracted with CMS to process Medicare claims for Part A and Part B, respectively. Under contracting reform, mandated by the 2003 MMA, new contracting entities known as Medicare Administrative Contractors (MACs) will merge Part A and Part B claims processing under a single authority. These new administrative authorities will be phased in, with all contracts required

and durable medical equipment claims; Program Safeguard Contractors (PSCs); and Recovery Audit Contractors (RACs).

Office of Research, Development, and Information

The Office of Research, Development and Information (ORDI) designs and conducts research on health care programs, studies their impact on beneficiaries, providers, plans and other partners and customers. As part of this research, ORDI sometimes develops new tools to measure the quality and efficiency of care. ORDI is also the component responsible for designing and conducting demonstrations to test innovations in payment policy.

Council on Technology and Innovation

The CTI was established in 2004 under Section 942(b) of the Medicare Prescription Drug Improvement and Modernization Act (MMA) of 2003 to serve as a coordination point for those components of CMS that are responsible for policy development and implementation affecting new and emerging medical technology and to coordinate the exchange of information on new technology between CMS and other entities that make similar decisions. The CTI is composed of senior CMS staff and clinicians and is chaired by an Executive Coordinator appointed by the Secretary of the Department of Health and Human Services. CTI facilitates discussions on coverage, coding, and payment issues of unusual complexity or controversy; accelerate and improve coordination of these processes; improves supply of evidence for new medical technologies; and facilitates the exchange of information with other federal agencies to devise clinical trials or registries that better meet the evidence needs to support coverage, coding and payment decisions.

Openness and Transparency of Processes

CMS maintains open channels of communication between outside entities and the components of CMS charged with making coverage, coding, and payment decisions remain open. CMS continues to preserve liaisons with beneficiaries, provider groups, industry associations, patient organizations, medical associations, investors, and other parties that relate to their assigned subject areas.

CMS periodically hosts Open Door Forums or Town Hall Meetings in order to better hear from and interact with those providers, beneficiaries, manufacturers, and other stakeholders interested in coverage, coding, payment and other issues. These forums encourage dialogue between CMS officials and stakeholders about policies under development or issues that arise with existing procedures. Notice of Town Hall Meetings is published in the *Federal Register* and specific information about Open Door forums can be found on the CMS website at: http://www.cms.hhs.gov/opendoorforums/.

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to be operating under the MAC structure by October 1, 2011. Additional information on contracting reform is on the CMS website at: http://www.cms.hhs.gov/MedicareContractingReform/

Many of CMS' policies are developed with the assistance of advisory committees or in collaboration with outside groups. Meetings of these groups are usually held in a public forum and interested parties may be invited to participate or comment. These groups include, but are not limited to, the Medical Evidence Development & Coverage Advisory Committee (MedCAC), the Advisory Panel on Ambulatory Payment Classification Groups (APC Panel), the National Committee on Vital and Health Statistics (NCVHS), American Hospital Association Editorial Advisory Board for the Coding Clinic, and the Practicing Physicians Advisory Committee (PPAC). Activities of these and other groups that help CMS develop policies for new health care technologies and ways that interested parties may stay informed of their activities are described in more detail in subsequent chapters of this guide.

Coordination with Outside Entities

CMS is strengthening its ties to health care technology stakeholders by developing collaborations with organizations that facilitate health care innovation. Collaborations help provide early insights into emerging technologies that may play a major role in reducing disease burden or improving health in the future.

CMS is working to speed Medicare beneficiary access to new and innovative medical products through closer coordination with the FDA. The Agencies are also exploring ways to ensure that when CMS needs to make coverage, coding, and/or payment decisions, it has access to timely and accurate FDA information regarding the technology at issue.

Increased Beneficiary Involvement

CMS has taken steps to encourage communication with beneficiary advocates in order to inform policy decisions. In June 2005, CMS appointed six patient advocates to the MedCAC as voting members, at least one of whom will sit on each MedCAC panel. The consumer representatives and industry representatives maintain their non-voting status and also participate in the MedCAC reviews.

The patient advocacy coordinator, from the CMS Office of External Affairs, orchestrates all patient advocate activities throughout the Agency. Providing a direct link between patient advocacy groups and CMS, this position is responsible for communicating coverage and payment regulatory decisions and issues to Agency constituents and special interest populations affected by these policies.

Contact Information

Information on CTI initiatives and activities is located on the CMS website at http://www.cms.hhs.gov/CouncilonTechInnov/01_overview.asp .

Stakeholders with further questions about Medicare's coverage, coding, and payment processes, or who want further guidance about how they can navigate these processes, can contact the Council at CTI@cms.hhs.gov .

COVERAGE

Medicare covers various items and services for its beneficiaries. The vast majority of coverage policy is determined on a local level by the Medicare contractors that pay Medicare claims. However, in certain cases, Medicare deems it appropriate to develop criteria for coverage via a national coverage determination (NCD).

This chapter provides general and historical information concerning the NCD process, and summarizes the local coverage determination (LCD) process.

National Coverage Determination (NCD)

NCDs are developed by CMS to describe the nationwide conditions for Medicare coverage for a specific item or service. NCDs generally outline the conditions for which a service is considered to be covered (or not covered) under §1862(a)(1) of the Act or other applicable provisions of the Act. NCDs are usually issued as program instructions. Once published in a CMS program instruction, an NCD is binding on all Medicare contractors, FIs, Quality Improvement Organizations (QIOs, formerly known as Peer Review Organizations or PROs) and Program Safeguard Contractors (PSCs). NCDs also are binding on Qualified Independent Contractors (QICs) and Administrative Law Judges (ALJ) during the claim appeal process. (See 42 CFR § 405.732, 42 CFR § 405.860, and 42 C.F.R. 405.1060).

The contractors shall apply NCDs when reviewing claims for items and services addressed by NCDs.

Medicare Advantage (Part C) health plans are required to cover all items and services that are offered under part A and B. Thus, plans must cover items and services that are covered under an NCD. NCDs do not apply to Part D plans.

NCDs should not be confused with "National Coverage Requests" or "Coverage Decision Memoranda."

NCD Process

The NCD process consists of three major steps: 1) initiation, 2) review, and 3) completion. CMS initiates the NCD process by “opening” the NCD. This is announced to the public by posting a “tracking sheet” on the CMS coverage web site. NCD reviews pertain to reviews of particular items and services to determine whether they meet the statutory requirements. Development of a complete, formal request for an NCD can be initiated either by an outside party or internally by CMS staff. Please refer to the following link which outlines how to request a complete and formal NCD: http://www.cms.hhs.gov/DeterminationProcess/02_howtorequestanNCD.asp

Time Frames

Time frames required for the NCD process are statutory, as mandated by the MMA. The time frame does not begin until CMS formally accepts an NCD request. When the volume of formal requests is heavy, CMS may set priorities – reviewing applications for technologies likely to have a greater impact on the Medicare program and its beneficiaries before those with lesser impacts. Once a completed request is accepted, CMS notifies the requester and posts a tracking sheet announcing the NCD review on the coverage website.

For NCD requests not requiring an external technology assessment (TA) or Medicare Evidence Development & Coverage Advisory Committee (MedCAC) review, CMS must post a proposed decision no later than six months after the date CMS accepts the completed formal request. For NCDs that require either a TA or MedCAC review, or both, the proposed decision must be posted no later than nine months after the date CMS accepts the completed request. The NCD process timeline is illustrated in a schematic located at http://www.cms.hhs.gov/DeterminationProcess/Downloads/8a.pdf

The NCD process can be found at http://www.cms.hhs.gov/DeterminationProcess/. Note: CMS refers to the National Coverage Analysis (NCA) process as the NCD process.

Technology Assessments

TAs are systematic reviews of evidence, conducted and coordinated by CMS staff to review relevant evidence and inform a determination if the item or service is reasonable and necessary. To minimize bias, systematic reviews emphasize a comprehensive search of all potentially relevant medical and scientific articles and use explicit, reproducible criteria in the selection of articles for review. Primary research designs and study characteristics are appraised in accordance with a hierarchy of medical evidence. Data are summarized and the evidence is appraised to assess its validity (how credible it is), clinical relevance (its applicability in real health care settings), and weight (magnitude of effect).

CMS' staff generally performs TAs internally but may contract with an external party to perform a TA. A guidance document on the CMS website describes the factors CMS considers in commissioning external TAs, posted at http://www.cms.hhs.gov/center/coverage.asp

Medicare Evidence Development & Coverage Advisory Committee

For coverage topics that are highly controversial or have a major potential impact on the Medicare program or its beneficiaries, CMS may draw on the expertise of the MedCAC. The primary role of the MedCAC is to provide independent, expert advice to assist CMS in making sound coverage decisions for the topic under review. The MedCAC reviews

and evaluates medical literature and TAs, listens to testimony, deliberates and after arriving at a considered judgment provides CMS with recommendations as to the strength of the evidence reviewed. The MedCAC may also be requested to comment on pertinent aspects of a proposal being considered under CMS' demonstration authority.

The CMS website contains an overview of the MedCAC, a guidance document entitled *Factors CMS Considers in Referring Topics to the Medicare Evidence Development & Coverage Advisory Committee*; the MedCAC's charter; the 1998 Federal Register notice that established the MedCAC (formerly known as the MCAC); the current roster of MedCAC members; and other informational materials. Additional information can be found at http://www.cms.hhs.gov/FACA/02_MedCAC.asp#TopOfPage

Decision Memoranda

CMS posts on its Web site proposed and final decision memoranda. The decision memoranda inform interested parties of CMS' analysis, describe the clinical position that CMS intends to implement and provide background on how CMS reached its decision.

NCD Implementation

The NCD is the formal instruction to the Medicare claims processing contractors regarding how to process claims (when to pay, when not to pay, pay only when certain clinical conditions are met). Appropriate payment or other changes to accommodate the coverage decision are effective at the time a final decision is posted to the CMS website. In most instances CMS implements an NCD through the change management process and provides detailed coding and billing instructions. The instructions specify appropriate coding and detail how the NCD criteria are to be effectuated in the claims processing systems. Those instructions have a specific effective date dictating when claims will be processed according to the new criteria. The contractors implement the NCD within their own jurisdictions and may subsequently develop LCDs or policy articles to supplement the NCD. NCDs are binding on all Medicare administrative contractors.

Coverage with Evidence Development

Under the concept of coverage with evidence development (CED), an NCD that requires prospective data collection and additional patient protections in place as a condition of coverage are known as coverage with appropriateness determination (CAD) and coverage with study participation (CSP), respectively. The purpose of CED is to provide Medicare coverage for a particular item or service and to develop evidence of the effectiveness on the care provided to beneficiaries. An example of an NCD with CAD is Positron Emission Tomography for Brain, Cervical, Ovarian, Pancreatic, Small Cell Lung, and Testicular Cancers. Examples of NCDs that require CSP are Continuous Positive Airway Pressure Therapy for Obstructive Sleep Apnea and Computed Tomographic Angiography. For more information on CED see https://www.cms.hhs.gov/mcd/ncpc_view_document.asp?id=8 .

Local Coverage Determination (LCD)

Section 522 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA) created and defined the term "local coverage determination" (LCD) as a decision by a contractor whether to cover a particular service on a contractor-wide basis in accordance with Section 1862 (a)(1)(A) of the Social Security Act (i.e., that the item or service is reasonable and necessary). LCDs may be developed in the absence of an NCD or as a supplement to an NCD as long as the LCD policy does not conflict with national policy.
Medicare contractors previously developed Local Medical Review Policies (LMRPs) as vehicles for local policy. In 2003, CMS instructed the contractors to create LCDs and convert all LMRPs into LCDs. CMS further instructed that all other guidance from contractors should be published in a contractor article

Local Coverage Determination Time Frames

Unlike the NCD time clock that begins with the acceptance of a formal request to open an NCD, the time clock for an LCD begins with the initiation of a minimum 45-day comment period following publication of a draft LCD. During this time, comments on the draft LCD must be solicited from several outside parties, including affected health professionals, other contractors, providers, and QIOs. In addition to the draft LCD comment period, contractors provide open meetings for the purpose of discussing draft LCDs prior to presenting the policy to the CAC. Once the contractor has considered all the comments and developed the final LCD, it must be published on Medicare's coverage website. A minimum notice period of 45 days is required prior to the effective date of implementation.

Reconsiderations of NCDs and LCDs

Any interested party may request a reconsideration of the benefit category determination or any other provision of an existing NCD or LCD by submitting a formal request in writing to CMS or the local contractor, respectively. A formal request for reconsideration must include either (1) new information that was not considered during the initial determination, or (2) arguments that the NCD or the LCD decision materially misinterpreted the applicable statutory provisions, the applicable regulatory provisions, or the existing evidence at the time the determination was made. Contractors must consider all LCD reconsiderations requests from beneficiaries residing or receiving care in the contractor's jurisdiction; providers doing business in the contractor's jurisdiction; and any interested party doing business in the contractor's jurisdiction. A reconsideration request – once accepted– goes through the same process as an initial NCD or LCD. The reconsideration process permits experts to re-evaluate the evidentiary basis for a decision.

Appeals of NCDs and LCDs

Distinct from reconsiderations of NCDs and LCDs or appeals of claims denials, section 1869(f) of the Act creates a process of independent review for beneficiaries to challenge NCDs and LCDs. These independent reviews are subject to strict limitations. Only an aggrieved party may seek review of an NCD or LCD. An "aggrieved party" is a beneficiary (or the estate of a beneficiary) who is entitled to Part A benefits, enrolled under Part B, or both, and is in need of coverage for an item or service that is denied based on the applicable NCD or LCD (regardless of whether or not the item or service was received) and has received written documentation from the treating physician of the need for the item or service.[3]

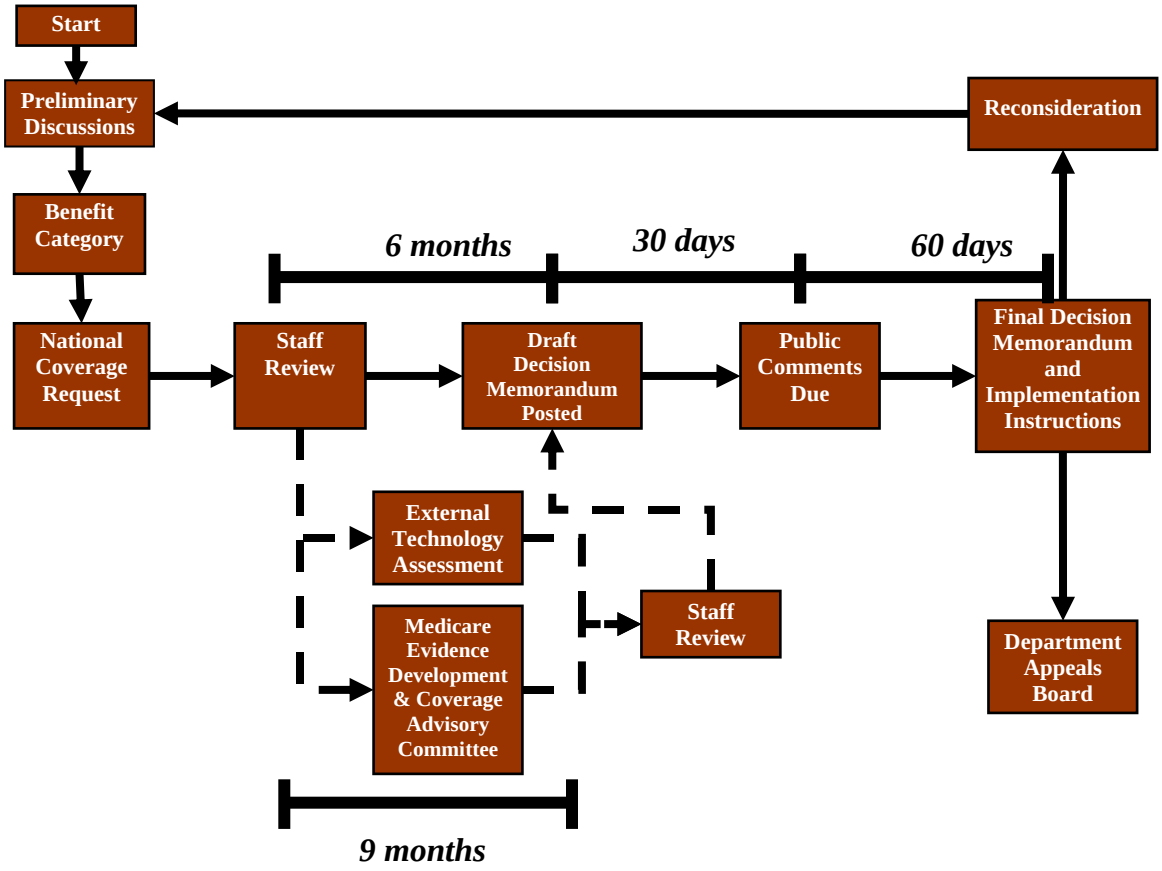
Regulations governing the appeals process are established at 42 C.F.R. Part 426.

Appeals of Claim Denials

Any beneficiary has the right to appeal a claim denial. This process results in the review of an individual claim denial, but it does not include a review of the validity or underlying evidentiary basis for an NCD and LCD.

[3] The aggrieved party may also be the estate of such a beneficiary who filed a timely complaint prior to death.

National Coverage Determination Process



CODING

For information on Coding:
http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/
http://www.cms.hhs.gov/MedHCPCSGenInfo/
http://www.cms.hhs.gov/ICD10/

Each year CMS processes more than one billion health care claims, comprising 20 percent of all health care claims processed in the United States. Use of standardized coding systems is essential for Medicare and other health insurance programs to ensure that claims are processed in an orderly and consistent manner. Standardized coding systems provide a uniform language for nationwide communication of medical, surgical, and diagnostic items and services for use in medical education, research, and development of guidelines for medical care review.

A major goal of an effective code set is to strike a balance that sufficiently identifies and differentiates items and services, and also results in a manageable system that health care professionals and administrative staff can efficiently use in submitting claims. Regular and predictable updates that accommodate new technology and changes in medical practice, without the administrative burden to health care providers of sporadic updates, increases confidence that the most current code sets are utilized.

Coding is distinct from coverage of a new technology; assignment of a new code does not automatically imply coverage by any payer. However, for items and services newly covered by Medicare, CMS may assign either a similar existing code, a miscellaneous code (e.g., a not otherwise classified code or a not otherwise specified code), or a temporary code for payment purposes, pending consideration of whether a unique code is needed.

This chapter discusses the coding systems used on Medicare claims; the statutory authority for coding use; general principles for coding updates; and a description of the ICD-9-CM and HCPCS code sets, including how to request a coding change, operational guidance, and a look to the future. A chart that compares the application cycles for new and revised code sets is located at the end of this chapter.

Statutory Authority - HIPAA

Recognizing the increasing role of electronic transactions between providers and insurers and the confusion and inefficiencies resulting from diverse ways of handling these transactions, the Congress required, in the administrative simplification title of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), adoption and use of national standards governing the nature and content of electronic transactions. This guide will focus on the HIPAA requirements related to national code sets, including associated operational guidelines.

To meet the HIPAA requirements for the adoption of transaction and code set standards, the Secretary of the Department of Health and Human Services (HHS), in a final rule issued in the August 17, 2000 *Federal Register*, designated six code sets as national standard code sets for use in standard electronic transactions throughout the United States:

- International Classification of Diseases, 9th Edition, Clinical Modification, Volumes 1 and 2 (tabular list and alphabetic index, respectively, of diseases);
- International Classification of Diseases, 9th Edition, Clinical Modification, Volume 3, (tabular list and alphabetic index of procedures);
- Healthcare Common Procedure Coding System;
- Current Procedural Terminology, 4th Edition;
- National Drug Codes; and
- Code on Dental Procedures and Nomenclature.

All entities covered by the HIPAA administrative simplification requirements, including health plans and health care providers, were required to be in compliance with the electronic transactions code set standards by October 16, 2003.

ICD-9-CM and HCPCS Coding Systems

The following standardized coding systems are used for processing Medicare claims:

- International Classification of Diseases, 9th Edition, Clinical Modification (ICD-9-CM); and

- Healthcare Common Procedure Coding System (HCPCS). HCPCS is divided into two principal subsystems:

    - Level I, comprised of CPT[4] codes
    - Level II

ICD-9-CM consists of codes for diagnoses and for hospital inpatient procedures. HCPCS consists of codes for items and services furnished in outpatient settings such as hospital outpatient departments, physicians' offices, and patients' homes.

General Principles for Coding Updates

The ICD-9-CM and HCPCS code sets are updated at least annually and in some cases more frequently. Each code set has a standardized, open process for developing new, unique codes as necessary. In most instances new technologies can be adequately described by existing codes, but in other cases new or revised codes may be warranted. The frequency of updates reflects a balance between the desire to rapidly recognize new technology within code sets and the need to provide users of the code sets with a stable, predictable update and business cycle. When code sets are updated, the updates must be disseminated, coding manuals revised, and medical records, billing software, and other

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systems changed to accommodate the new and revised codes. Coders must be educated on and prepared for changes in codes to ensure they are accurately utilizing the codes to best describe the diagnoses identified and the items and services delivered. Predictable update cycles allow providers to plan for and manage the necessary changes in coding practices and systems. The process for requesting updates to each code set is described in greater detail below. Also, refer to the Code Set Comparison Chart at the end of this chapter for a timetable of key milestones for each code set.

ICD-9-CM

For information on ICD-9-CM:
http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/

The ICD-9-CM is a modified version of the ICD-9 system developed by the World Health Organization. CM refers to a "clinical modification" developed for the United States, where it has been in use since 1979. ICD-9-CM contains three volumes of information. Volume 1 contains the diagnosis codes that every health care provider needs for billing. Volume 2 is an alphabetical index of Volume 1. Volume 3 contains procedure codes, which are used for billing inpatient hospital stays in the diagnosis-related group (DRG)[5] payment system. ICD-9-CM procedure codes describe the procedure performed and may also indicate insertion of a device, such as a pacemaker or hip replacement. Procedure codes do not specifically describe all the devices and products used during a procedure, such as wound closing devices, specific catheters, or surgical tools.

ICD-9-CM codes have a hierarchal structure using a framework that corresponds to body systems. The diagnosis codes contain 3, 4, or 5 numeric digits, with the longer codes providing greater detail. Procedure codes are limited to 3 or 4 digits, while diagnoses can be coded with up to 5 digits. For FY 2008, the ICD-9-CM code set includes 13,677 diagnosis codes and 3,768 procedure codes, or a total of 17,445 codes. The number of new or revised codes varies depending on the number of requests for codes. Since FY 2004, over 175 new procedure codes have been added to the code sets and over 50 additional codes have been refined to better describe the procedure.

Example of ICD-9-CM Codes

Diagnosis Code: xxx.xx

- First 3 digits – specifies disease
- 4th digit – gives additional detail
- 5th digit – specifies subtype of disease

Procedure Code: xx.xx

- First 2 digits – specifies anatomical region
- Last 2 digits – specifies procedure

Responsibility for maintaining the ICD-9-CM is divided between two agencies in HHS: (1) the National Center for Health Statistics (NCHS) within the Centers for Disease Control for maintenance of the classification of diagnoses, and (2) the CMS for maintenance of the classification of procedures. Since the federal government maintains

[5] DRGs are discussed in greater detail in the Payment chapter and also in the Acute Inpatient Prospective Payment System Fact Sheet located on the CMS website: http://www.cms.hhs.gov/MLNProducts/downloads/AcutePaymtSysfctsht.pdf.

the ICD-9-CM code set, it is in the public domain, and providers, insurers, and others can use the system without paying user fees.

The ICD-9-CM Coordination and Maintenance Committee

For information on the ICD-9-CM Coordination and Maintenance Committee, addenda, and summary reports:

http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/03_meetings.asp#TopOfPage
http://www.cdc.gov/nchs/icd9.htm

The ICD-9-CM Coordination and Maintenance (C&M) Committee, co-chaired by representatives from NCHS and CMS, considers requests to create new ICD-9-CM codes or to revise codes for greater utility. The C&M Committee holds public meetings twice a year, generally in March and September, to discuss proposed revisions. The C&M Committee's role is advisory, and no decisions are made at these meetings. The Director of NCHS and the Administrator of CMS make all final diagnosis and procedure coding decisions, respectively.

Information on the C&M Committee meetings is posted on the CMS website. The agenda for upcoming meetings is posted approximately one month prior to the meeting. Official code revision packages, which are referred to as addenda, and summary reports are available on the CMS website for procedure codes and the NCHS website for diagnosis codes. Summary reports for the most recent meeting include the deadline for comments, the scheduled dates for the next meeting, the deadline for receipt of modification proposals, and the mailing address and e-mail address to send either modification proposals or comments on proposals.

Process for Requesting a Revision to ICD-9-CM

For information on how to request new/revised ICD-9-CM procedure codes:

http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/02_newrevisedcodes.asp#TopOfPage

Interested parties are instructed to submit recommendations for ICD-9-CM modification to the C&M Committee two months prior to a scheduled meeting. Proposals for new codes should include a description of the requested code and the rationale for why the new code is needed. [See side box.] Supporting references and literature may also be submitted. Proposals should be consistent with the structure and conventions of the classification system.

Upon review of the request, a decision is made on whether to include the topic on the meeting agenda. If included, a lead coding analyst is assigned and will contact the requestor to discuss the submitted proposal. A background paper, including CMS recommendations on proposed coding revisions, is shared with the requestor prior to the meeting. The requestor is given the opportunity (or may select a speaker) to make a presentation on the clinical nature of the procedure at the upcoming C&M meeting.

Speakers are allowed approximately 20 minutes to present the topic. The lead coding analyst then leads a discussion of possible code revisions, including alternative suggestions for consideration. No decisions are made at the meeting.

Public comments are encouraged both at the meetings and in writing. The meeting participants are encouraged to ask questions concerning the clinical and coding issues and to offer recommendations. A summary report is posted on the CMS website within approximately one month of the meeting. The public is offered an opportunity to make additional written comments by mail or e-mail before the end of the comment period imposed by the C&M Committee.

Request for a Procedure Code

A request should include:

- Background information on the procedure
- Patients on whom the procedure is performed
- Outcomes and any complications
- Manner in which the procedure is currently coded
- Discussion of reasons the existing ICD-9-CM codes do not adequately capture the procedure
- Recommended options for new or revised code titles

Examples of procedure code papers can be found in summary reports of previous meetings located on the CMS website at http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/03_meetings.asp#TopOfPage

Recommendations and comments are carefully reviewed and evaluated before any final decisions are made by NCHS or CMS. Finalized ICD-9-CM code revisions and proposed DRG[6] assignments are published in the inpatient prospective payment system (IPPS) notice of proposed rulemaking (NPRM) on or around April 1 of each year. The public may not comment on the listed codes because they are final, but may comment on the proposed DRG assignments during the IPPS NPRM comment period. Due to timing constraints, proposals from the Spring C&M meeting may not be finalized for inclusion in the IPPS proposed rule.

The IPPS final rule, published on or about August 1 of each year, includes the finalized DRG assignments and repeats the finalized ICD-9-CM codes. The ICD-9-CM codes that were finalized after the spring publication of the proposed IPPS rule appear in the final rule with an asterisk by the code number.

Publishers and vendors then prepare ICD-9-CM coding books, software, and other publications. The revised codes are implemented on October 1 of each year to coincide with the updating of the IPPS.

New technology coding topics presented during the Fall C&M Committee meeting are considered for an April 1 implementation if a strong and convincing case is made by the requester at the Committee's public meeting. The request must identify the reason why a new code is needed in April for purposes of the IPPS new technology process. The participants at the meeting and those reviewing the Committee meeting summary report are provided an opportunity to comment on the expedited request. The April 1 implementation exception for new technology, though available since 2004, has not yet been utilized.

[6] Ibid.

ICD-9 Coding Guidance

The official ICD-9-CM coding guidelines are posted on the National Center for Health Statistics (NCHS) website at:
http://www.cdc.gov/nchs/datawh/ftpserv/ftpicd9/ftpicd9.htm#guide

Operational coding advice and guidelines for ICD-9-CM are published quarterly by the American Hospital Association (AHA) in *Coding Clinic for ICD-9-CM (Coding Clinic).* The Editorial Advisory Board (EAB) for *Coding Clinic* consists of representatives of AHA, the American Health Information Management Association (AHIMA), NCHS, CMS, the American Medical Association (AMA), the American College of Surgeons, and other hospital coders and physicians. Four of those parties (AHA, AHIMA, NCHS, and CMS) are identified as Cooperating Parties for *Coding Clinic*. The Cooperating Parties must agree on the coding guidance before it can be published in the *Coding Clinic*. Anyone may send issues to AHA for EAB discussion.

AHA supplies copies of the *Coding Clinic* to the Quality Improvement Organizations (QIOs) for use as official coding advice in reviewing the accuracy of coding for Medicare claims submitted by hospitals. Copies are also available on the AHA website (www.ahacentraloffice.org) for a fee.

A Look to the Future

For information on the ICD-10 coding system:
http://www.cms.hhs.gov/ICD10/

ICD-9-CM, which is over 28 years old, is exhibiting technical obsolescence. One aspect of this problem is a significant limitation on the availability of new codes to accommodate new technology and changes in medical practice. The Department of Health and Human Services is considering issuing regulations through notice and comment rule-making that would replace ICD-9-CM as a national standard code set with an updated version called ICD-10-CM for identifying diagnoses and the ICD-10-Procedure Coding System (PCS) for identifying procedures. The ICD-10-PCS encompasses an updated hierarchical structure and uses seven-character alphanumeric codes permitting a more detailed and flexible inpatient coding system.

HCPCS

For information on HCPCS:
http://www.cms.hhs.gov/MedHCPCSGenInfo/
http://www.cms.hhs.gov/MedHCPCSGenInfo/Downloads/LevelIICodingProcedures113005.pdf

The Healthcare Common Procedure Coding System (HCPCS)[7] is the standard code set for items and services furnished in outpatient settings, such as physicians' offices, hospital outpatient departments, and patients' homes. The HCPCS code set is divided into two principal subsystems, referred to as Level I and Level II. Level I consists of the Current Procedural Terminology (CPT[8]), an alpha-numeric coding system maintained by the American Medical Association to identify medical services and procedures furnished by physicians and other health care professionals. Level II of the HCPCS is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes. Because Medicare and other insurers cover a variety of services, supplies, and equipment that are not identified by CPT codes, the Level II HCPCS codes were established for use in submitting claims for these items. Level II codes are maintained and distributed by CMS, taking into consideration input from all insurers including Medicare, Medicaid, and private payer organizations.

Level I HCPCS - Current Procedural Terminology

The AMA developed the Current Procedural Terminology in 1966, and the version currently in use is the fourth edition. There are three categories of CPT[9] codes:

- Category I codes consist of five numeric digits and represent procedures and services performed by physicians, other health care professionals, and facilities. Category I codes are divided into six sections: Evaluation and Management; Anesthesiology; Surgery; Radiology; Pathology and Laboratory; and Medicine. Each section is further divided into subsections based on anatomic system, procedure or condition.

- Category II codes are performance measurement codes that support data collection for services that are generally agreed to contribute to positive health outcomes. Category II codes have five characters – four numbers and then the letter F.

[7] Prior to 2001, this code set was called the HCFA Common Procedure Coding System after the previous name of the Agency. In 2001, the former Health Care Financing Administration (HCFA) became the Centers for Medicare & Medicaid Services.
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- Category III codes are emerging technology codes that support data collection for services that do not yet have FDA approval or are not widely used. Category III codes have five characters – four numbers followed by the letter T.[10]

Requesting a Revision to Level I HCPCS (CPT[11])

Proposals to add, modify, or delete CPT codes are considered by the CPT Editorial Panel, a 17-member group comprised of representatives from the AMA, private health insurers, the American Hospital Association, the Health Care Professionals Advisory Committee, and CMS. The CPT Editorial Panel is supported in its efforts by the CPT Advisory Committee, which is made up of representatives of more than 90 medical specialty societies and other health care professional organizations.

CPT Coding Request

The AMA recommends that parties interested in requesting a CPT code answer several questions before submitting a request:

- Is the suggestion a fragmentation of an existing procedure/service?
- Can the suggested procedure / service be reported by using two or more existing codes?
- Does the suggested procedure / service represent a distinct service?
- Why aren't the existing codes adequate?

Source: AMA website

The CPT Editorial Panel meets regularly, at least three times a year. Applications for new codes are accepted on a rolling basis but proposed CPT changes must be received at least four months in advance for consideration at the next meeting. An application form and directions to request changes to CPT are available on the AMA website.

For information on how to apply for a CPT code:
http://www.ama-assn.org/ama/pub/category/3866.html

Category I CPT codes are updated annually to reflect changes in medical technology and practice. Coding changes are effective for use on January 1 of each year. The AMA prepares each annual update so that the new CPT books are available in the fall of each year preceding their effective date to allow for implementation.

Category I vaccine product codes, Category II, and Category III codes are typically released either January 1 or July 1 of a given CPT cycle and become effective six months subsequent to the date of release, e.g., codes released on January 1 are effective July 1, allowing 6 months for implementation, and codes released on July 1 are effective January 1.

CPT[12] Coding Guidance

[10] Unlike Category I codes, the AMA Relative Value Update Committee (RUC) does not make recommendations for relative values relation to resource use for Category II and Category III Codes. (The RUC provides information on resource use to be used in establishing relative weights under the Medicare Physician Fee Schedule, which is described in the Payment chapter.)

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For information on CPT Coding Guidance:
https://catalog.ama-assn.org/Catalog/home.jsp?checkXwho=done
http://www.healthforum.com/healthforum/html/data_statistics/Data_Products.html

The AMA produces a number of CPT manuals and publications. A catalog of their products is available on the AMA website. CPT is copyrighted by the AMA. The AMA requires a license to use CPT in a product or publication. Information on the licensing agreement is available on the AMA website.

In 2005, the AHA and CMS entered into an agreement for the establishment of a Clearinghouse to handle inquiries on established HCPCS usage and to publish the results of those inquiries to assist providers in properly using established HCPCS codes. The purpose of the Clearinghouse is to provide interpretation and explanation on the proper use of Level I HCPCS (CPT-4) codes for hospital providers and certain Level II HCPCS codes for hospitals, physicians, and other health professionals who bill Medicare.

CMS works closely with the AHA and the AMA to promote consistency of interpretation of the basic principles of HCPCS coding by institutional providers, and to prevent any wide divergence between HCPCS coding by institutional providers and the recommendations made by the AMA's CPT-4 advisory panel for the physician community. The AHA Clearinghouse is supported by the HCPCS Editorial Advisory Board (EAB) and functions in a manner similar to the Coding Clinic for ICD-9-CM. Coding guidance provided by the HCPCS EAB is published quarterly by the AHA in the *Coding Clinic for HCPCS.* CMS is working with the AHA, AHIMA, and other members of the HCPCS EAB to develop the Clearinghouse into the kind of valuable resource for users of HCPCS that the Coding Clinic has become for ICD-9-CM users.

Level II HCPCS

Level II HCPCS codes are used primarily to identify products and services not included in the CPT codes, such as drugs and biologicals, or durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) used in outpatient settings such as hospital outpatient departments, physicians' offices, and patients' homes. The development and use of Level II of the HCPCS began in the 1980's. Level II HCPCS codes are also referred to as alpha-numeric codes because they consist of a single alphabetical letter followed by four numeric digits.

Currently, Level II HCPCS codes represent approximately 4,000 separate categories of like items or services that encompass millions of products from different manufacturers. A descriptor is assigned to a code that provides the definition of the items and services that can be billed using that code. To avoid any appearance of endorsement of a particular product through HCPCS, brand or trade names are not used to describe the products represented by a code, except as required by the statute for payment purposes (e.g., single source drugs). Level II HCPCS are in the public domain and a free, downloadable file is available on the CMS HCPCS website at www.cms.hhs.gov/medhcpcsgeninfo. Tape or

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disk versions can be purchased from the National Technical Information Service (NTIS) by phone at 703-487-4650 or by e-mail at orders@ntis.fedworld.gov. Paper copies can be purchased through the Government Printing Office (GPO). The American Dental Association (ADA) maintains and copyrights the Current Dental Terminology (CDT) code sets. Therefore, CMS has an agreement with the ADA to include and publish CDT codes or dental codes (D codes) in the HCPCS Level II code set.

Permanent National HCPCS

Level II HCPCS includes several types of codes that have different purposes. Permanent national HCPCS code sets are distributed and maintained by the CMS. The CMS HCPCS Workgroup considers each coding request and recommends whether a change to the national permanent codes is warranted. Recommendations for a revision to the HCPCS are reviewed at regularly scheduled meetings of the CMS HCPCS Workgroup. CMS makes final HCPCS coding decisions. The HCPCS Decision Tree, developed by the CTI, is a helpful tool for determining if a new technology warrants a unique code and is posted on the CMS website at: http://www.cms.hhs.gov/MedHCPCSGenInfo/Downloads/decisiontree.pdf.

Types of Permanent Level II HCPCS Codes*

A codes	Ambulance, medical and surgical supplies, administrative, miscellaneous, and investigational
B codes	Enteral and parenteral nutrition
D codes	Current Dental Terminology (CDT) codes
E codes	Durable Medical Equipment (DME)
J codes	Drugs that are not self-administered and generally not administered orally, inhalation solutions, chemotherapy drugs
L codes	Orthotics and prosthetics
M codes	Other Medical Services
P codes	Pathology and laboratory services, and blood products
R codes	Diagnostic radiology services
U codes	Modifiers (There are currently no codes in this section.)
V codes	Vision Services (e.g., lenses), audiology, and speech-language pathology

*"Miscellaneous" and "Not Otherwise Classified" codes exist in almost every alphabetic code section.

Permanent national codes are updated once a year on January 1. Codes are broken down into general categories that include a series of codes for drugs[13], orthotics and prosthetics, vision services, etc. A list of the categories of permanent national codes appears in the side box.

[13] Medicare uses the 5 character alphanumeric HCPCS to identify Part B drugs rather than the 11-digit National Drug Codes (NDCs). NDCs are used by retail pharmacies and by state Medicaid agencies to identify drugs, and in Medicare Parts C and D. Some billing systems used by professional and institutional providers do not use NDC codes.

Temporary National HCPCS

Like permanent national HCPCS codes, temporary national HCPCS codes are distributed and maintained by the CMS. Temporary codes allow CMS the flexibility to establish codes that are needed to meet the national program operating needs of a particular insurer, i.e., Medicare, Medicaid, private insurance sector, before the next January 1 annual update for permanent national codes or until consensus can be achieved on a permanent national code. Temporary codes are intended to meet the national program operational needs of a particular insurer (Medicare, Medicaid, or the private insurance sector) that are not addressed by an already existing national code. They are developed based on programmatic needs and cannot be requested by other parties. The CMS HCPCS Workgroup has set aside certain sections of the HCPCS code set for temporary codes for specific items or types of insurers (for example, G codes are used by Medicare to identify professional health care procedures and services that would otherwise be coded in CPT[14] but for which there are no suitable CPT codes). [See side box.]

Types of Temporary Level II HCPCS Codes

C codes	Items and services for outpatient use, including pass-through devices, pass-through drugs and biologicals, brachytherapy sources, and new technology and certain other services.
G codes	Professional health care procedures and services that would otherwise be coded in CPT but for which there are no CPT codes.
H codes	Mental health services for which State Medicaid agencies are mandated by State law to establish separate codes.
K codes	Used by the DME MACs when permanent national codes do not include codes needed to implement a medical review policy.
Q codes	Drugs, biologicals and other medical equipment or services not identified by national Level II codes, but for which codes are needed for Medicare claims processing.
S codes	Used primarily by private insurers to report drugs, services, and supplies for which there are no permanent national codes, but for which codes are needed to implement policies, programs, or claims processing. Also may be used by Medicaid program, but typically not payable by Medicare.
T codes	Used primarily by State Medicaid agencies for items for which there are no permanent national codes and for which codes are necessary to meet a national Medicaid program operating need. Typically not used by Medicare but can be used by private insurers.

Temporary codes do not have established expiration dates. Although temporary codes may be established to meet the programmatic needs of specific payers, other payers may elect to use these codes.

Temporary codes can be added, changed, or deleted on a quarterly basis. Once established, temporary codes for Medicare are usually implemented within 90 days, the time needed to prepare and issue policy and implementation instructions, enter the new

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code into the claims processing computer systems, and initiate user education. Quarterly updates to the Level II HCPCS codes can be found on the CMS HCPCS website.

Code Modifiers

In some instances, insurers instruct providers and suppliers that a HCPCS code must be accompanied by a code modifier to provide additional information regarding the service or item identified by the HCPCS code. Modifiers are used when the information provided by a HCPCS code descriptor needs to be supplemented to identify specific circumstances that may apply to an item or service and that may have implications for the level of or conditions of payment for a particular insurer. For example, a UE modifier is used when the DME item identified by a HCPCS code is "used equipment," a NU modifier is used for "new equipment." The level II HCPCS modifiers are either alpha-numeric or two letters.

Dental Codes

Dental codes are a separate category of national codes. The Current Dental Terminology (CDT) is maintained and copyrighted by the American Dental Association (ADA). It lists codes for billing for dental procedures and supplies. CDT codes, while a separate standard code set adopted under HIPAA, reside within HCPCS Level II. Decisions regarding the revision, deletion, or addition of CDT codes are made by the ADA and not the CMS HCPCS Workgroup. HHS has an agreement with the ADA to include CDT as a set of HCPCS level II codes for use in billing for dental services. CDT manuals are available for purchase on the ADA website. Users of CDT codes must enter an agreement with the ADA.

Miscellaneous Codes

The absence of a specific code for a distinct category of products does not preclude a provider’s or supplier's ability to submit claims to private or public insurers and does not affect patient access to products. Miscellaneous codes are available for assignment when there is no existing national code that adequately describes the item or service for billing. Miscellaneous codes allow providers and suppliers to begin billing immediately for a service or item as soon as it is allowed to be marketed by the FDA, even though there may be no distinct code that describes the service or item. A miscellaneous code may be assigned by an insurer for use while a request for a new code is being considered under the HCPCS review process, permitting establishment of a claims history to support the need for a national permanent code. The use of miscellaneous codes also helps avoid the inefficiency and administrative burden of assigning distinct codes for items or services that are rarely furnished or for which insurers expect to receive few claims.

Except for hospital outpatient claims, Medicare claims with miscellaneous codes are generally manually reviewed by the claims contractors. The provider must provide a clear description of the billed item or service, pricing information, and documentation to explain why the item or service is needed by the beneficiary. Under the hospital outpatient prospective payment system (OPPS), unlisted procedure codes are assigned to

the lowest level APC within the clinical category that includes the unlisted code. The assignment of an unlisted code to the lowest level APC in the clinical category in which the code falls provides a reasonable means for interim payment until such time as there is a code that specifically describes the services being performed and paid. It encourages the creation of codes where appropriate and mitigates against overpayment of services that are not clearly identified on the bill. For new technologies that encompass complete services but may not have yet been granted a specific CPT[15] code, the New Technology APC payment mechanism is available under the OPPS.

Before using a miscellaneous code on a claim form, a provider or supplier should check with the entity that will receive the claim to determine whether there is a specific code that should be used rather than a miscellaneous code. Interested parties that believe a unique code is warranted should submit a request to modify the HCPCS in accordance with the established process.

Requesting a Revision to a Level II HCPCS Code

For information on the HCPCS application process:
http://www.cms.hhs.gov/MedHCPCSGenInfo/01a_Application_Form_and_Instructions.asp#TopOfPage

Any interested party may submit a request to modify the HCPCS Level II national code set. Detailed information regarding the process and the format for submitting a request is available on the CMS HCPCS website. In addition to the information requested in this format, a requestor should submit any descriptive material, including the manufacturer's product literature and information that is helpful in understanding the medical features of the item.

The HCPCS coding review process is an ongoing, continuous process. Requests may be submitted at any time throughout the year. Requests that are received and complete by January 3 of the current year are considered for inclusion in the next annual update, with implementation, January 1 of the following year. Requests received or completed after January 3, and requests received earlier that require additional evaluation, are included in a later HCPCS review cycle.

Three types of coding revisions may be requested:

- Addition of a permanent code
- Revision of the language used to describe an existing code
- Discontinuation of an existing code

The CMS website includes a list of all public requests for modifications to the code set submitted in the current coding cycle along with CMS' preliminary coding decision and rationale. Interested parties may submit comments regarding these code requests and preliminary decisions to the CMS HCPCS Workgroup by sending an e-mail via the

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HCPCS website. CMS hosts a series of annual HCPCS public meetings that provide an open forum for interested parties to make oral presentations or submit written comments in response to the preliminary HCPCS coding decisions. Comments regarding code requests, received by the date of the public meeting at which the code request is discussed, are included as part of the Workgroup's review when it reconvenes to reconsider all requests on the public meeting agendas. Notice of HCPCS Public Meetings is published in the Federal Register each year.

HCPCS Coding Guidance

The following resources are available on the CMS HCPCS website at:
http://www.cms.hhs.gov/MedHCPCSGenInfo/

- HCPCS decision tree and definitions,
- current HCPCS, Quarterly and Annual Updates,
- alphabetical index of HCPCS codes by type of service or product,
- alphabetical table of drugs for which there are Level II codes,
- newly established temporary codes, and
- effective dates for code use,
- HCPCS Level II coding process information and criteria,
- HCPCS Level II code modification application and instructions,
- Summaries of code applications, and
- Public meeting agendas and summaries.

CODE SET COMPARISON CHART							
	Timing			Volume	Transparency		
CODE SET	**Application Deadline**	**Effective Date**	**Length of Cycle**	**Average Number of Applications in Cycle**	**Provide Detailed Application Summaries**	**Publish Preliminary Decisions**	**Public Input**
HCPCS II	January 3	January 1 of the following year	12 months + Quarterly Updates	200	Yes – published 1 month prior to Public Meetings	Yes	Public Meetings May & April each year
CPT16	November 1	January 1 of the following 2nd year	15 months + Quarterly Updates	200 (Review is divided into committees and sub-committees, who report back to 1 group)	No	No	Public may attend voting meeting. Votes are silent.
CDT	October 1 thru October 1 of the following year	15 to 27 months following receipt of application	15 to 27 months	120	No	No	Public may attend voting meeting. Votes are known.
ICD-9	October 1	October 1 of the following year	12 months + Quarterly Updates	CMS processes 10 – 25 procedure applications ---------- NCVHS processes 25 diagnosis applications	Yes – provided at public meeting	No	Public Meeting May
	Between July and the following January	October of the following year (procedures) or extra year (diagnoses)	9 - 27 months	CMS processes 10 – 25 procedure applications ---------- NCVHS processes 25-35 diagnosis applications	Yes – provided at public meeting	No	Public Meetings March & September

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PAYMENT

For information on Medicare FFS payment systems:
http://www.cms.hhs.gov/home/medicare.asp
http://www.cms.hhs.gov/center/provider.asp
http://www.medpac.gov/payment_basics.cfm

Medicare is the single largest payer for health care services in the United States. The majority of beneficiaries, over 80 percent in FY 2007, are enrolled in Medicare Parts A and B, which provide fee-for-service (FFS) insurance. Medicare contracts with claims administrators (known as Medicare contractors) to process more than one billion FFS claims from over one million providers, totaling over $283 billion in FY 2006.

Medicare pays for most items and services on a prospective rather than cost basis. A prospective, fixed payment system allows for better resource planning by providers, offers bundled services or items for care management, and provides incentives for efficiencies.

While the methodologies for determining the payment rates vary by setting, in most cases the payments are based on a statutory formula that calculates the relative relationship between the average cost for performing a service and the average cost of performing all services in the same setting. The relative cost for a service is represented by a number called the relative weight. To determine the payment, the relative weight is generally multiplied by a fixed dollar amount or rate.

Under most FFS payment systems, changes to the relative weights are budget-neutral such that increasing the relative weight (and payment) for one item or service will decrease payments for all other items and services under that system. Updates to the fixed dollar amount or rate for inflation or other factors that result in a change in total expenditures are not generally budget-neutral.

Each FFS payment system is usually updated annually. CMS proposes payment rates and policy changes for the following year and those rates and changes are open for public comment. In some instances, CMS also holds public meetings to gather additional input.

This chapter focuses on the payment systems for acute and ambulatory care settings that are most likely to see the introduction of new technology – inpatient acute care hospitals, hospital outpatient departments, and physician offices. This chapter also describes the payment mechanisms for specific items such as the limited drugs covered under Part B, clinical laboratory tests, and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), including information on the new competitive bidding program for certain DMEPOS.

Payment systems for other settings such as skilled nursing facilities, home health agencies, inpatient rehabilitation facilities, inpatient psychiatric facilities, long-term care hospitals, end-stage renal disease facilities, ambulatory surgical centers, and ambulance

suppliers are similar in their prospective nature and general design to the payment systems profiled in this chapter. A chart of the rulemaking cycles for the profiled FFS payment systems is located at the end of this chapter.

Inpatient Prospective Payment System

For information on the IPPS:
http://www.cms.hhs.gov/AcuteInpatientPPS/
http://www.medpac.gov/documents/MedPAC_Payment_Basics_07_hospital.pdf

IPPS Payments

For information on determining IPPS payment:
http://www.cms.hhs.gov/AcuteInpatientPPS/02_stepspps.asp#TopOfPage

The hospital inpatient prospective payment system (IPPS) makes payments to acute care hospitals for each Medicare patient, or case, treated. Hospitals are paid based on the average national resource use for treating patients in similar circumstances, not the specific cost of treating each individual patient. With few exceptions, Medicare does not pay separately for individual items or services.[17] Physicians and hospital staff determine the appropriate course of treatment, and hospitals receive a bundled payment for the covered inpatient facility services provided to the Medicare patient. Hospitals receive one IPPS payment per Medicare case at discharge that equates to the total Medicare payment for the facility costs of caring for that Medicare patient. Physicians are paid separately under the Physician Fee Schedule for their professional services provided during the inpatient stay.

Medicare Severity Diagnosis-Related Groups

For information on MS-DRGs:
http://www.cms.hhs.gov/reports/downloads/WR434Z1.pdf

Under the IPPS, each case is categorized into a Diagnosis-Related Group (DRG) depending on the patient's diagnosis, the procedures performed, complicating conditions, age, and discharge status. Each DRG has a payment weight assigned to it, based on the average resources used to treat Medicare patients in that DRG compared to the cost of cases in other DRGs. The weights are recalibrated annually. For FY 2008, CMS revised the DRG payment system by adopting 745 Medicare Severity (MS)-DRGs to replace the previously existing 538 DRGs to better recognize severity of illness. The changes did not result in cost savings to Medicare but increase payment amounts to hospitals treating more severely ill and costlier patients, and decrease payment amounts to hospitals treating less severely ill patients.

[17] Certain costs are paid outside of the IPPS. For example, heart, liver, lung and kidney acquisition costs incurred by an approved transplant facility are paid on a reasonable cost basis.

Standardized Amounts

For information on wage index:
http://www.cms.hhs.gov/AcuteInpatientPPS/03_wageindex.asp

The base payment unit for IPPS is called the standardized amount. The standardized amount is based on hospital charges per Medicare discharge that are adjusted to account for differences in certain hospital costs, such as the patient case-mix and wage rates. These payment amounts are increased annually by an update factor. Update factors are set by Congress and are intended to account for annual inflation while maintaining incentives for hospitals to be efficient.

The standardized amount is divided into labor-related and non-labor-related shares. After the labor-related share is adjusted by a wage index applicable to the area where the hospital is located, it is added back to the non-labor-related share.[18] This wage-adjusted standardized amount is then multiplied by the DRG relative weight to determine the payment for the case. The standardized amount is subject to other adjustments that may be applied to each case that a qualifying hospital treats or applied only to specific cases as described below.

Add-on Payments – DSH

For information on DSH:
http://www.cms.hhs.gov/AcuteInpatientPPS/05_dsh.asp#TopOfPage

If a hospital treats a high percentage of low-income patients, it receives a percentage add-on payment applied to the wage-adjusted base payment rate of the DRG for each case it treats. This add-on, known as the disproportionate share hospital (DSH) adjustment, varies depending on several factors, including the percentage of low-income patients served.

Add-on Payments – IME

For information on IME:
http://www.cms.hhs.gov/AcuteInpatientPPS/07_ime.asp#TopOfPage

If the hospital trains residents in an approved medical residency program, it receives a percentage add-on payment for each case, known as the indirect medical education (IME) adjustment. This payment varies with the number of residents the hospital is training and the hospital's number of inpatient beds. Teaching hospitals also receive a separate payment outside the IPPS, based on the number of residents, for Medicare's share of the hospital's direct cost of medical education.

[18] If the hospital is located in Alaska or Hawaii, the non-labor share is also adjusted by a cost of living adjustment factor.

Outlier Payments

For information on outlier payments:
http://www.cms.hhs.gov/AcuteInpatientPPS/04_outlier.asp#TopOfPage

Case-specific adjustments are made for high cost cases called outliers. The outlier payment is designed to protect the hospital from large financial losses due to unusually expensive cases, which can reflect the use of advanced technology. The costs of a new technology are included in the determination of whether a case qualifies for an outlier payment. The outlier payment is determined by comparing the total cost of caring for a particular case to the DRG payment for that case, including and DSH or IME payments and payments for new medical services and technologies, plus a fixed dollar amount that is set in regulation.[19] The outlier payment is added to the wage-adjusted base payment rate for the DRG, plus any DSH or IME adjustments and any applicable add-on payment for new technologies, as described below.

Add-on Payments – New Technology

For information on IPPS new technology add-on payments:
http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage

The IPPS is designed to adapt to changing technology through year-to-year adjustments in DRG weights based on historical cost data. In theory, if new technologies lead to better care but are more expensive, or if they lead to more efficient care and are less expensive, hospitals will eventually receive appropriate payment as the DRG weights are adjusted over time to reflect the impact of fluctuating costs. In practice, however, there are concerns that the system may be slow to react to rapidly evolving technological advancements. Hospitals may experience a financial disadvantage as they provide more expensive products and services to Medicare beneficiaries while waiting for DRG payments to reflect the higher costs. As an incentive for hospitals to adopt new technologies during the period before their costs are recognized in the DRG weights, certain new medical services or technologies may be eligible for new technology add-on payments. The new technology add-on payment policy provides additional payments for eligible high cost cases without significantly eroding the incentives provided by a payment system based on averages.

[19] The costs are determined by applying the hospital's cost-to-charge ratio (CCR) – the percentage of charges that costs have represented for the hospital in the past -- to the hospital's charges for the case. Those costs are compared to a DRG-specific fixed loss threshold, which is the sum of the DRG payment for the case, including any add-on payments (new technology, indirect medical education, disproportionate share adjustment), plus a fixed loss amount. CMS sets the fixed loss amount each year at a level projected to generate outlier payments equal to 5.1 percent of total payments under the IPPS. Medicare then pays 80 percent of hospitals' costs above the fixed loss threshold.

To qualify for add-on payments, a service or technology must be new, represent a substantial clinical improvement over predecessor technology, and be high cost relative to the DRG payment that would normally be paid. Since it can take two to three years for reflection of cost data in the calculation of the DRG weights, technologies generally are considered new for two to three years after they become available. Applicants must demonstrate that their product offers substantial clinical improvement, relative to technologies previously available, in the diagnosis or treatment of Medicare beneficiaries. Applicants must submit a formal request including a full description of the clinical applications of the technology, the results of any clinical evaluations demonstrating that the new technology represents a substantial clinical improvement, and data to demonstrate that the technology meets the high cost threshold, which is published in the IPPS final rule.

Items Qualifying for New Technology Add-on Payments

Item	Condition Treated	Years
Xigris®	Severe sepsis	FY2003 FY2004
InFuse™ Bone Graft	Spinal fusion	FY2004 FY2005
Kinetra® Implantable Neurostimulator	Essential tremor and Parkinson's disease	FY2005
Cardiac Resynchronization Therapy with Defibrillation	Chronic, moderate to severe heart failure	FY2005
Endovascular Graft Repair of the Thoracic Aorta (GORE TAG)	Thoracic aorta aneurysms	FY2006
Restore® Rechargeable Implantable Neurostimulator	Chronic, intractable pain	FY2006
X STOP Interspinous Process Decompression System	Back and leg pain (lumbar spinal stenosis)	FY 2007
No new items approved	N/A	FY 2008

The approved items in this table represent half of all applications submitted from FY 2003-2008 requiring judgment based on the criteria for an add-on payment. The other half was disapproved either because the applications were not substantially different from older technologies or because they failed to meet the criteria for substantial clinical improvement or high cost.

The high cost threshold for eligible items is the lesser of:

- 75 percent of the standardized payment amount, increased based on the national case-weighted ratio of costs to charges,

- or -

- 75 percent of one standard deviation of the geometric mean standardized charge for cases in the DRG involved with the technology, or the case-weighted average of all relevant DRGs, if the new technology could be assigned to many different DRGs.

Although any interested party may submit an application for a new technology add-on payment, applications often come from the manufacturer of a new drug or device. A preliminary discussion on whether or not new technologies qualify for add-on payments are published in the IPPS proposed rule and are open to public comment. CMS posts the deadlines for submittal of the applications on its web site well in advance of the expected IPPS proposed rule publication to allow time for receipt and careful consideration of the applications. CMS will generally accept partial or Phase I applications if some of the necessary information (e.g., FDA approval) is expected but has not been obtained by the initial deadline. The deadline for completed or Phase II applications is generally at the end of the calendar year for add-on payments effective October 1 of the following year. Go to http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp to find the current year's deadline.

The actual add-on payments are based on the cost to hospitals for the new technology. A new technology add-on payment is made if the total covered costs of the patient discharge exceed the DRG payment of the case (including adjustments for IME and DSH, but excluding outlier payments). The total covered costs are calculated by applying the cost-to-charge ratio (that is used for inpatient outlier purposes) to the total covered charges of the discharge.

If the costs of the discharge exceed the full DRG payment, the additional payment amount equals the lesser of the following:

- 50 percent of the costs of the new medical service or technology; or
- 50 percent of the amount by which the total covered costs of the case (as determined above) exceed the standard DRG payment, plus any applicable outlier payments if the costs of the case exceed the DRG, plus adjustments for IME and DSH.

Hospital Outpatient Prospective Payment System

For information on the OPPS:
http://www.cnms.hhs.gov/HospitalOutpatientPPS/
http://www.medpac.gov/documents/MedPAC_Payment_Basics_07_OPD.pdf

Bundled Payments

Under the hospital outpatient prospective payment system (OPPS), hospitals are generally paid for each covered service they provide to Medicare beneficiaries at prospectively established rates based on the national median cost of performing similar services. As under the IPPS, the payment received for each service is generally a bundled payment for a group that reflects the total facility cost of providing the service. The payment bundle includes most implantable devices and low cost drugs. All supplies and equipment integral to performing a service are bundled into the estimate of the cost of the service. Therefore, OPPS group payments typically include the costs of the supportive and ancillary services required to perform the specific hospital outpatient

service, which are incorporated into the OPPS cost-based payment group weight. However, while the IPPS makes one bundled payment for all care provided during the inpatient stay, a hospital may receive multiple OPPS payments for a single outpatient encounter if multiple separately payable services are provided during that encounter. Physicians are paid separately under the Medicare Physician Fee Schedule for their professional services provided during outpatient encounters.

Ambulatory Payment Classifications

All items and services paid separately under the OPPS are assigned to payment groups called Ambulatory Payment Classifications (APCs), which are intended to group together items and services that are similar in clinical characteristics and cost. APC relative payment weights are based on estimated cost. There are several types of APCs that represent types of items or services paid under the OPPS:

- Procedure or visit APCs (clinical APCs),
- Pass-through drug, biological, or device APCs,
- Nonpass-through drug APCs,
- Brachytherapy source and blood product APCs, and
- New Technology APCs

Items and services under the OPPS are reported on claims with CPT[20] codes and Level II HCPCS codes (See Coding Chapter). Payment for these codes may be either paid separately or packaged. As noted above, OPPS cost-based relative payment weights reflect the packaged costs of items and/or services that are usually supportive and ancillary to a separately payable service. Services in each clinical APC are similar clinically and in terms of the resources they require. By law, the highest-cost service in an APC generally cannot cost more than two times the lowest-cost service in the APC (often referred to as the 2 times rule). Each year CMS reviews and adjusts, as necessary, the APC groupings and updates the relative payment weights to ensure that they are consistent with clinical practice and comport with the requirements of the 2 times rule. Exceptions to the 2 times rule may be made for low volume services or other special cases.

Advisory Panel on Ambulatory Payment Classification Groups

For information on the APC Panel:
http://cms.hhs.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp

Generally, twice a year CMS holds a meeting of the Advisory Panel on Ambulatory Payment Classification Groups (APC Panel), a federal advisory committee comprised of hospital representatives with expertise as clinicians or in hospital administration, coding, and billing. The APC Panel meetings are open to the public, with notification of upcoming meetings published in the Federal Register. The meetings generally occur in

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late winter and late summer to provide input into the development of the proposed and final OPPS rules for the following calendar year. The APC Panel hears presentations from the public about the need for changes in the structure of the APCs, and reviews data on the utilization and cost of the services in question. The Panel makes recommendations to CMS about potential changes in APCs. CMS addresses these recommendations during the annual rulemaking cycle.

APC Payment Rates

Hospital-specific overall and department-specific cost-to-charge ratios (CCRs) are applied to a hospital's charges for services in the most recent full year hospital claims data to determine estimated costs per service for purposes of rate setting. The costs are standardized on each claim to reflect the labor costs in the geographic area in which the hospital is located using the IPPS pre-reclassification hospital wage index. The median cost, including packaged costs, of all services assigned to each clinical APC is then calculated. CMS calculates a scaled APC weight that reflects the relative median cost of the services within the APC compared to the median cost of the mid-level clinic visit, scaled to maintain the total payment weight under the prospective payment system. The scaled relative weight for the APC is multiplied by a base payment unit called the conversion factor to determine the APC payment rate. The conversion factor is updated annually for changes in hospital operating input costs. The conversion factor also is adjusted annually to account for anticipated outlier payments and pass-through payments and incorporates budget neutrality adjustments for the wage index and rural adjustment.

All items within an APC have the same payment rate, although there are policies, such as the multiple surgical procedure reduction, that may result in two procedures in the same APC being paid different amounts. In CY 2008, separately payable drugs and biologicals are paid based upon an average sales price (ASP) methodology, calculated from sales data submitted to CMS by drug manufacturers.

Outlier Payments

In addition to the APC payment, hospitals may receive outlier payments for high cost services. To receive an outlier payment, the hospital's charges, reduced to cost by application of its overall CCR, must exceed the OPPS payment for the service by both a fixed threshold ($1,575 for CY 2008) and by 1.75 times (for CY 2008) the APC payment. The fixed loss threshold exists to ensure that outlier payments are made for unusually high costs that are incurred in providing care to the most costly patients receiving expensive and complex services. When a service meets the criteria for outlier payment, the hospital receives an outlier payment that equals 50 percent of the difference between its costs and the OPPS APC payment. For CY 2008, the OPPS sets the criteria to limit the outlier payments to 1 percent of the estimated total payments made under the OPPS.

Transitional Corridor Payments

Cancer hospitals and children's hospitals receive additional transitional corridor payments that make up any difference between what the hospital receives under the OPPS and what it would have received under the cost reimbursement methodology that existed prior to implementation of the OPPS. These hospitals are permanently held harmless from a decline in payments below their pre-BBA amount as a result of the implementation of the OPPS. In addition, the statute provides for some transitional corridor payments through CY 2009 to small rural hospitals that are not also sole community hospitals. The statute also provides for some transitional corridor payments to all small sole community hospitals for CY 2009.

Rural Sole Community Hospital Adjustment

The MMA instructed the Secretary to conduct a study comparing urban and rural hospital costs and provided the authority to adjust OPPS payments to rural hospitals payments by January 1, 2006, if rural hospital costs were determined to be greater than urban hospital costs. Based on an analysis of rural and urban hospital costs that showed that rural sole community hospital were the only class of rural hospitals that were significantly more costly then urban hospitals, CMS implemented a budget neutral 7.1 percent payment increase for rural sole community hospitals in CY 2006, which has been continued during CY 2007 and CY 2008 and includes the small number of hospitals classified as essential access community hospitals.

New Technology APCs

For information on the New Technology APC application process:
http://www.cms.hhs.gov/HospitalOutpatientPPS/Downloads/newtechapc.pdf

New technology services, including surgical procedures, diagnostic tests, and other procedures, may be assigned to a New Technology APC. Assignment to a New Technology APC allows CMS to gather actual cost data about the service before it is placed in an APC with other clinically similar services. The predetermined New Technology APC payment is based on CMS's best estimated cost of the new service.

New Technology APCs provide payment for complete services or procedures that cannot be appropriately billed under an existing HCPCS code or combination of codes. Components or items that are part of a more comprehensive service are not eligible for placement in a New Technology APC. Although any interested party may apply to have a new service assigned to a New Technology APC, most applications are received from manufacturers or hospitals. To qualify for assignment to a New Technology APC, the service must not be adequately represented in the claims data being used for the most current annual OPPS payment update, and may not qualify for transitional pass-through payment.

Applications for a New Technology APC assignment can be submitted at any point in the year and are considered for inclusion in a quarterly update that is at least four months away from the date of submission to allow time for analysis, decision-making, and systems changes. For example, to be considered for the July 1 update, applications must be received by the first business day in March. The time period for a determination may be extended if an application is incomplete, if further information is required, or if a more extensive evaluation is required to determine eligibility.

Assignment to a New Technology APC is temporary. Services and procedures are moved from a New Technology APC to a clinical APC once sufficient claims data are available for the technology to appropriately place it with services that are clinically similar and have similar resource use. The transition from a New Technology APC to a clinical APC is done through the rulemaking process, where the proposed clinical APC assignment is open to public comment.

Transitional Pass-Through Payments

To develop an appropriate APC payment for a procedure, CMS must be able to determine the costs to the hospital of performing the procedure, including the cost of drugs, biologicals, and devices that may be used in the respective procedure. Prior to the implementation of the OPPS in 2000, there was concern that CMS did not have sufficient hospital cost data to determine the appropriate cost for some items. Transitional pass-through payments may provide additional payment for new devices, drugs, and biologicals for two to three years while CMS gathers additional data on the cost of those items.[21] These new items are used in existing procedures, and those procedures are assigned to existing APCs. As noted above, complete new procedures do not qualify for transitional pass-through payments but may be considered for placement in a New Technology APC.

Pro-Rata Reduction

By law, the total amount of pass-through payments in a year is limited to a percentage of total payments under the OPPS. For 2000 through 2003, the pass-through limit was 2.5 percent of total payments. In 2004 and future years, the limit is 2.0 percent of total payments. If CMS estimates that pass-through payments will exceed that limit, a uniform (pro-rata) reduction to all pass-through payments is required. Pro-rata reductions apply only to transitional pass-through payments for a particular year. To date, 2002 is the only year in which a pro-rata reduction was necessary. Changes required by MMA in the payment for drugs under the OPPS reduce the likelihood of a pro-rata reduction in the future.

Transitional Pass-Through Payments: Devices

For information on the transitional pass-through device application process: http://www.cms.hhs.gov/HospitalOutpatientPPS/04_passthrough_payment.asp#TopOfPage

[21] When OPPS was first implemented, certain items that were considered current, rather than new, qualified for pass-through payments. The pass-through payment period for those items ended at the end of 2002.

The additional payment for devices eligible for pass-through payment is the difference between the hospital's cost for the new device and the payment amount attributed to similar devices in the APC payment rate for the procedure with which the eligible device is used. The pass-through device cost is determined by adjusting a hospital's charges for the item to cost using its overall CCR. The cost of similar devices, if any, which are identified in the procedural APC with which the pass-through device is associated, is then subtracted from the device's cost to determine the pass-through payment amount for the device.

Examples of Expired Device Categories

Category	Active Pass-through Years
Pacemaker, dual chamber, non rate-responsive	2001, 2002
Lead, neurostimulator (implantable)	2001, 2002
Lead, coronary venous	2003, 2004
Integrated keratoprosthesis	2004, 2005
Rechargeable neurostimulator	2006, 2007

As with applications for assignment to New Technology APCs, applications for pass-through status can be submitted at any point in the year and are considered for inclusion in a quarterly update that is at least four months away from the date of submission. The time period for a determination may be extended if an application is incomplete, if further information is required, or if a more extensive evaluation is required to determine eligibility. To qualify, an item must have costs that are not insignificant compared with APC payments that would otherwise be made, including the costs of similar items. Applications for new devices must also demonstrate a substantial clinical improvement in the diagnosis or treatment of an illness or injury.

Transitional pass-through payments for devices are based on categories of devices. CMS can create a new category of pass-through devices to include an item only if that item cannot be described by any current or previous pass-through device category. Comments received during past rulemaking cycles indicated that some of the previous and existing category descriptors were thought by some observers to be overly broad and may preclude some new technologies from qualifying for establishment of a new device category for pass-through payment. In response to this concern CMS modified the regulations to permit, beginning in CY 2006, creation of an additional category for devices that meet all of the criteria required to establish a new category for pass-through payment in instances where an existing or previously existing category descriptor does not appropriately describe the new type of device. The above web site link describes two tests that must be met to determine whether an existing or previously existing category appropriately describes the new device. Creation of an additional category may require clarification or refinement of the descriptors of previous categories. A determination regarding the revision of category descriptors is made on a case-by-case basis and implemented prospectively.

Transitional Pass-Through Payments: Drugs and Biologicals

For information on transitional pass-through drug payments:
http://www.cms.hhs.gov/HospitalOutpatientPPS/04_passthrough_payment.asp#TopOfPage

For information on Average Sales Price:
http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/

For a listing of services that identifies the drugs and biologicals that are separately paid under the OPPS, along with their payment rates:
http://www.cms.hhs.gov/HospitalOutpatientPPS/AU/list.asp#TopOfPage

The purpose of transitional pass-through payments for new drugs and biologicals is to enable beneficiaries' access to technologies that are too new to be captured in the data used to determine APC payment rates. Section 1833 (t)(b)(D) of the Act specifies the pass-through payment amount is the amount by which the amount as determined under section 1842 (o) (referring to payment under the ASP methodology or under the Competitive Acquisition Program (CAP)) exceeds the otherwise applicable payment for the drug or biological. For CY 2008, payment for drugs and biologicals with pass-through status is made at ASP+6 percent or the CAP rate if the product is offered under the Part B drug CAP, while payment for separately paid drugs and biologicals without pass-through status is made at ASP+5 percent. Approval of a drug or biological for a transitional pass-through payment under the OPPS is not contingent on prior assignment of a national HCPCS code. New drugs and biologicals that receive transitional pass-through status are assigned a product-specific HCPCS code.

Non Transitional Pass-Through: Drugs and Biologicals

For new drugs and biologicals that do not have a specific HCPCS code, the MMA requires CMS to pay hospital outpatient departments at 95 percent of its average wholesale price (AWP). To implement the MMA provision, CMS instructed hospitals to bill for a new drug or biological using a new HCPCS code, C9399 (unclassified drug or biological), and the National Drug Code (NDC) for the product. The OPPS payment system flags the code for manual pricing by the Medicare contractor. The contractor sets the payment rate at 95 percent of AWP using the Red Book or other recognized compendium.

Physician Fee Schedule

For information on the PFS:
http://www.cms.hhs.gov/PhysicianFeeSched/
http://www.cms.hhs.gov/center/physician.asp
http://www.medpac.gov/documents/MedPAC_Payment_Basics_07_Physician.pdf

Payments per Service

Physicians' services, including surgery, consultation, and home, office and institutional visits, are considered professional services performed by physicians. [22] Professional services and the items needed to perform a specific service (e.g., supplies, equipment, clinical and administrative staff, and office overhead expenses) are paid under a payment system known as the Medicare Physician Fee Schedule (PFS).

PFS payments are the product of the national relative value units for a service, the geographic practice cost indexes (GPCIs) for the area where the service is furnished, and the single "dollar" conversion factor. The conversion factor for physicians' services is updated annually by a formula specified in law.

Relative Value Units

For information on RVUs:
http://www.cms.hhs.gov/PFSlookup/03_PFS_Document.asp#TopOfPage
http://www.cms.hhs.gov/PFSlookup/

Each of the over 7,000 services paid under the PFS is divided into three components for purposes of establishing its relative value:

- physician work – reflecting the physician's time, effort, and technical skill required to render a service,
- practice expense – equipment, supplies, and office overhead items such as rent, employee wages, utilities, and
- malpractice insurance premiums.

Generally, each component of each physician service is assigned a uniform national relative value unit (RVU), a numerical value used to quantify the relative amount of resources required to perform each service under the Physician Fee Schedule. The law prohibits any differential in payment for a service based upon the specialty of the physician performing the service. The law requires a review of relative values at least once every five years.

[22] Under certain circumstances Medicare pays for physician services performed by non-physician practitioners, such as nurse practitioners, under the PFS if the service is performed incident to a physician's service.

The initial physician work RVUs used at the inception of the PFS were based primarily on a study of physician work conducted for CMS by the Harvard School of Public Health. The study valued each service on the basis of the relative physician work--time, effort, and skill--required to perform the service.

Practice expense RVUs for a service are based on the typical or average resources required to perform each service including the direct practice expense inputs for the type and amount of clinical staff time, disposable supplies, and equipment. Actual resources used may vary depending on the treatment of the specific patient or individual practice styles. .

Malpractice RVUS are based on malpractice premium data for the top 20 Medicare physician specialties. For each service, the malpractice RVU amount is the weighted average of the premiums for specialties that perform the service using the proportion of the total services provided by the specialty as the weight.

RUC

In establishing RVUs for new and revised codes, and for the 5-year review, CMS takes into consideration the recommendations of a committee sponsored by the American Medical Association (AMA). The Relative Value Update Committee (RUC) provides recommendations for work RVUs, and through the work of its Practice Expense Sub-committee, provides recommendations for practice expense resource inputs. Voting members of the RUC include representatives from medical specialties and others. The RUC recommendations are subject to review by CMS staff, physicians, contractor medical directors, specialty refinement panels of physicians, and the public through notice and comment rulemaking.

The current process provides an opportunity for all specialties to participate through the RUC in developing recommendations to CMS about relative values for new services. This multi-specialty feature of the system is important since the PFS, like the IPPS and OPPS, is a relative value payment system and not a cost-based reimbursement system. Increased payments for a service result in decreased payments for all other services.

Geographic Practice Cost Indexes

For information on GPCIs:
http://www.medpac.gov/publications/other_reports/Aug03_GPCI_2pgrKH.pdf

Payments under the PFS are adjusted for geographic variation in costs across 89 payment areas. A geographic practice cost index (GPCI) specific to the payment locality where the service is furnished is applied to each of the three relative value components of the PFS. The GPCIs are required by law to measure area cost differences compared to the national average for each of the three fee schedule relative value components.

Sustainable Growth Rate

For information on the SGR:
http://www.cms.hhs.gov/SustainableGRatesConFact/

The annual update to the PFS conversion factor is calculated based on a statutory formula which includes inflation in physicians' costs to provide care, and then is adjusted up or down by how actual national Medicare spending totals for physicians' services compare to a target rate of growth called the sustainable growth rate (SGR). If spending is less than the SGR, the physician payment update is increased, and if spending exceeds the SGR, the update is reduced. The SGR system was designed to constrain the rate of growth in Medicare physician spending and link it to growth in the overall economy, as well as to take into account physician control over volume and intensity of services. For purposes of calculating the SGR, physician services include clinical laboratory services and Part B drugs furnished incident to a physician service. In recent years, application of the SGR formula would have dictated reductions in the PFS conversion factor, but in all years since 2002, Congress has enacted legislation to hold payments constant or to provide a small increase.

Contractor-Priced Services
In some instances, an item or service coverable in a physician's office does not have a national payment rate under the PFS. In those cases, the Medicare contractor is required to determine the appropriate payment rate for the locality it serves. Most of the contractor-priced codes represent low volume items or services, or new items or services that are not accurately described by established procedure codes and therefore billed using not otherwise classified (NOC) codes. In setting the payment rate for a service represented by a contractor-priced code, the contractor medical director (CMD) typically gathers evidence on the relative amount of physician work and other physician resources required to perform the service. In setting the payment rate for an item represented by contractor-priced code, the CMD would typically gather information about the cost of the item through invoices or other means. Examples of contractor-priced items are those for radiopharmaceuticals provided in a physician's office.

Part B Drugs in the Physician's Office

For information on Part B drugs:
http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/
http://www.cms.hhs.gov/CompetitiveAcquisforBios/

For information on Part B Drug ASP:
http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/

Medicare Part B covers a limited number of drugs provided as part of (or incident to) a physician service, certain oral drugs specified by law, and drugs furnished as part of covered durable medical equipment. Medicare pays the physician or pharmacy for the drug provided to the beneficiary and does not pay pharmaceutical manufacturers directly.

Part B covered drugs include certain infused or injected drugs provided primarily by oncologists, rheumatologists, and urologists, and certain oral drugs such as immunosuppressives, anti-cancer drugs, and anti-nausea drugs used in conjunction with the treatment of cancer. Other oral drugs are covered under the Part D drug benefit, which uses a different payment mechanism.

Prior to 2004, Medicare paid for most drugs under Part B based on the lower of their actual charge or 95% of their average wholesale price (AWP). Medicare did not pay a separate fee to pharmacies with respect to most Part B drugs. Payment for supplying Part B covered drugs to beneficiaries was bundled into the payment for the drugs. In 2004, Medicare paid for Part B drugs based on the lower of their actual charge or 85% percent of their AWP, with certain exceptions.

Beginning with 2005, the MMA specified that certain Part B covered drugs are paid 106 percent of the average sales price (ASP) as computed based on manufacturer's average sales prices submitted to CMS quarterly by manufacturers. Drug payment amounts are updated quarterly based on the most recent manufacturer data. During any given quarter, CMS will calculate the next quarter's payment amounts based on the last quarter's manufacturer data. Therefore, many describe this process as having a two quarter lag.

The MMA also required Medicare to pay a supplying fee as determined appropriate by the Secretary to pharmacies for certain Medicare Part B covered drugs. In 2008, the supplying fee is set at $50 for the first immunosuppressive prescription after a beneficiary has received a transplant, $24 for the first prescription per month in all other instances, and $16 for all subsequent prescriptions within the 30-day period. Medicare pays a furnishing fee for items and services related to Medicare Part B covered blood clotting factor products. The furnishing fee payment amount for years after CY 2005 is increased annually by the percentage increase in the consumer price index for medical care for the 12 month period ending with June of the previous year. In 2008, this fee is $0.158 per unit of clotting factor. Medicare also pays a dispensing fee for nebulized inhalation drugs that are furnished as a part of covered DME. In 2008, the monthly fee is set at $33 except for the first month a beneficiary is receiving these drugs. In that case the fee is set at $57. Medicare pays $66 if a beneficiary receives a 90-day supply.

Competitive Acquisition Program

For information on the CAP program:
http://www.cms.hhs.gov/CompetitiveAcquisforBios/01_overview.asp

The MMA required that CMS develop a competitive acquisition program (CAP) for Part B drugs. CAP serves as an optional alternative method for physicians to acquire certain Part B injectable drugs that are administered in the office setting. Under the CAP, vendors bid for the opportunity to provide these specified products to physician offices. The vendor bills Medicare directly for the drugs and collects the coinsurance from the beneficiary. The physician orders the necessary drugs from the vendor and has no billing responsibilities for medications obtained from the vendor. The physician is still responsible for submitting claims for drug administration.

Clinical Laboratory Services

For information on clinical laboratory services:
http://www.cms.hhs.gov/ClinicalLabFeeSched/
http://www.cms.hhs.gov/center/clinical.asp
http://www.medpac.gov/documents/MedPAC_briefs_Payment_Basics_07_clinical_lab.pdf

Generally, Medicare pays for clinical diagnostic laboratory tests at the least of three possible amounts: the actual charge for the test submitted by the laboratory; the local fee schedule amount; or the national limitation amount (NLA). The local fee schedules were originally based on 60 percent of the prevailing charges for tests in each contractor locality for services rendered on or after July 1, 1984. The NLA is a percentage of the median value of all local fees for each test. The NLA is set at 74 percent of the median of the local fees for tests for which NLAs were established before January 1, 2001 and at 100 percent of the median for tests Medicare first paid for on or after January 1, 2001. Unlike the IPPS, the OPPS, and the PFS, the clinical laboratory fee schedule has no provision to permit routine changes in relative payment rates to reflect technological advances and other changes other over time.

Fee schedule amounts are generally updated each year by the change in the consumer price index. Congress has from time to time reduced this update. Most recently, MMA eliminated the update for calendar years 2004 through 2008. Beneficiaries do not pay cost-sharing for clinical laboratory services as they do for most other Medicare services.

The statute does not specify how to calculate fees for new tests. The MMA required CMS to establish annual procedures for consulting the public on how to establish payment for new lab test codes to be included in the annual update of the clinical laboratory fee schedule. For a clinical laboratory test that is assigned a new or substantially revised code in a particular year, CMS notifies the public that a new code has been created and invites the public to present comments on the appropriate basis for establishing a payment amount for the new code. CMS considers the comments presented at the public meeting and makes a list of its proposed determinations. The proposed determinations, the reasons for the determinations, and the data on which the determinations were based are made available to the public. The public is given an opportunity to submit comments. CMS then issues a list of final determinations for each new test.

Public Meetings Regarding New Products

CMS holds public meetings on proposed payment determinations for certain new codes representing both clinical laboratory and DME items. The meetings provide an opportunity for CMS to obtain industry and public reaction to preliminary recommendations regarding payment methodology for these codes.

Each public meeting is announced in the *Federal Register* 30 days prior to the meeting date. A detailed agenda and summary of the meeting is posted on the CMS website. [See Coding Chapter]

Depending on the nature of a new test, CMS uses one of two methods to determine payment. The first method, called cross-walking, is used for a new test that is similar to an existing test code, multiple existing test codes, or a portion of an existing test code. The new test code is assigned the existing local fee schedule amount and the existing NLA for the related test. Payment for the new test code is made at the lesser of the local fee schedule amount or the NLA. The second method, called gap-filling, is used when no comparable, existing test is available. Gap-filling requires each local contractor to develop a payment amount based on charges, costs, and other relevant factors for its locality. Local fees are established from the gap-fill amounts and become the basis for establishing the NLA for a new test code, multiple existing test codes, or a portion of an existing test code.

The public may request CMS to reevaluate its decision of whether a code should be priced by cross-walking or gap-filling. This reconsideration process, effective for new or revised codes assigned to HCPCS on or after January 1, 2008, provides the public with an additional opportunity to comment on CMS payment determinations.

Durable Medical Equipment, Prosthetics, Orthotics, and Supplies

For information on DMEPOS
http://www.cms.hhs.gov/DMEPOSFeeSched/
http://www.cms.hhs.gov/center/dme.asp

Medicare payment for most durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), including surgical dressings, therapeutic shoes, and parenteral and enteral nutrition, is based on the lower of the actual charge for the item or a fee schedule amount. The law specifies that the fee schedule amounts for each category of DMEPOS (inexpensive or other routinely purchased items, items requiring frequent and substantial servicing, customized items, oxygen and oxygen equipment, and other items of DME are to be based on average payments made under the previous reasonable charge methodology in a base year[23]. The fee schedule amounts are updated by annual covered item updates. The law also sets various ceiling and floor limits on the fee scheduled for different DMEPOS categories. The fee schedule amounts for DME and surgical dressings are statewide fee schedule amounts. The fee schedule amounts for prosthetic devices, prosthetics, orthotics, and therapeutic shoes are regional fee schedule amounts that are the weighted average of the state fee schedule amounts in each of 10 CMS regions. The fee schedule amounts for parenteral and enteral nutrition are national fee schedule amounts.

As with clinical laboratory services, the law does not specify how to calculate fee schedule amounts for new DME technology. Generally, gap-filling is used to calculate new DME fee schedule amounts by using either:

[23] The actual months from 1986 and 1987 included in the base year vary across different types of DME according to time periods specified in the law. Payment for surgical dressing fees is an exception and is calculated using a 1992 base period.

- Fee schedule amounts for comparable items; or
- Supplier or retail prices.

In cases where retail pricing information is used, the DME gap-filling methodology approximates historic reasonable charges by using current prices decreased by a deflation factor to approximate the base year price. The deflation factors are based on the percentage change in the consumer price index for urban consumers (CPI-U). Once this amount is determined, the amount is inflated to the current price using a percentage increase and the cumulative covered item update. The covered item updates are set in law and are often, but not always, the CPI-U.

Inherent Reasonableness

Inherent reasonableness (IR) is the authority provided to CMS to correct grossly excessive or deficient Medicare payment amounts for specific items and services under Part B that are not paid under the Physician Fee Schedule or a prospective payment system. Payments for DME and clinical laboratory services may be adjusted using IR. By law, IR determinations revise inherently unreasonable payment amounts when factors, including the following, result in grossly deficient or excessive payment amounts: Medicare and Medicaid are the sole or primary source of payment for the a category of items or services; the payment amounts do not reflect changing technology, increased facility with that technology, or changes in acquisition or production costs; or the payment amounts are grossly higher or lower than payment amounts made by other purchasers in comparable localities. Factors that may be considered in establishing a revised payment are the price markup, the differences in charges to Medicare and to other payers, and the cost necessary to produce the item or service.

Both CMS and the Medicare contractors may make IR determinations. The IR determinations made by CMS apply nationally. CMS will publish proposed and final notices in the Federal Register before adopting a new payment amount. The notice will provide the criteria and circumstances, if any, under which a contractor may grant an exception to the IR-adjusted amount.

IR adjustments are limited to a 15 percent increase or decrease in any given year. If a contractor is establishing a special payment limit using the inherent reasonableness authority, the contractor must inform the affected suppliers and Medicaid agencies of the proposed payment amounts and the factors considered in determining that amount. Contractors must also solicit comment on the proposed amount and evaluate those comments. Contractors must submit in writing any proposed IR adjustment to CMS. The adjustment may not be imposed until CMS informs the contractor that notification of the proposed adjustment has been received and the carrier has informed the affected suppliers and State Medicaid agencies of any limits it establishes. This policy is designed to make sure that full consideration is given to pertinent factors before limitations are set locally.

A Look to the Future

For more information:
http://www.cms.hhs.gov/center/asc.asp
http://www.cms.hhs.gov/center/dme.asp
http://www.cms.hhs.gov/center/clinical.asp
http://www.cms.hhs.gov/center/esrd.asp
http://www.whitehouse.gov/news/releases/2006/08/20060822-2.html
http://www.hhs.gov/valuedriven

The MMA requires significant changes in the future payment methodology for several items and services. In January 2008, CMS implemented a revised payment system for services provided in ambulatory surgical centers (ASCs). Like the OPPS, the ASC payment system has several hundred procedure classification groups with payment rates set using relative weights, a conversion factor, and adjustments for geographic differences. In addition, certain items and services assigned to New Technology APCs or with pass-through status under the OPPS may be paid under the ASC payment system. As described above, CMS will continue to expand the competitive bidding program for DMEPOS. CMS is also implementing a demonstration to test a similar process for acquiring clinical laboratory services.

As described above, CMS refines Medicare payment policy through annual rulemaking and responds to changes in clinical practice and industry operations. CMS is interested in public input on areas that need improvement at all stages of the rulemaking process but it is most helpful to receive recommendations as we develop the proposed rules to allow for full consideration of potential changes.

Value-based Purchasing

Medicare is rapidly transforming itself from a passive payer for services into an active purchaser of higher quality care by linking payment to the quality of care provided. This transformation will shift the focus of Medicare from reimbursing providers based solely on the volume of services furnished to reimbursing providers based on higher quality, more efficient health care. Value-based purchasing (VBP) initiatives use performance-based financial incentives and public reporting of quality information to encourage improvement in all aspects of quality, including patient safety. CMS' transformation of its role into that of an active purchaser responds to the President's Executive Order: Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs, and the Secretary of the Department of Health and Human Services' Value-Driven Health Care initiative.

CMS has implemented several VBP initiatives:

- The hospital setting has played a leading role in our VBP implementation. The current Reporting Hospital Quality Data for the Annual Payment Update (RHQDAPU) program ties a portion of the annual update for most hospitals reimbursed under the Inpatient Prospective Payment System (IPPS) to reporting on a

set of quality measures that is expanded and refined each year. CMS has developed a Medicare Hospital Value-Based Purchasing Plan that builds on RHQDAPU and ties a portion of a hospital's payment to its performance on a set of quality measures. CMS intends to develop a hospital VBP measure set that comprehensively addresses clinical quality, patient safety, patient experience, and resource use.

- Another Medicare Part A VBP initiative addresses hospital-acquired conditions. In the FY 2008 IPPS Final Rule, CMS identified hospital-acquired conditions that will no longer trigger the higher paying CC or MCC MS-DRG as complicating conditions when not present on admission for discharges beginning October 1, 2008. These conditions include serious preventable events (*e.g.*, object left in after surgery, blood incompatibility, or air embolism), urinary and venous catheter-associated infections, and other conditions like pressure ulcers and falls. The IPPS FY 2009 final rule added conditions to those selected during IPPS FY 2008 rulemaking. The additional conditions are: (1) surgical site infections following certain orthopedic procedures and bariatric surgery for obesity; (2) manifestations of poor blood sugar control, such as diabetic ketoacidosis and hypoglycemic coma; and (3) deep vein thrombosis or pulmonary embolism associated with total knee and hip replacement procedures. All of the conditions will have payment implications when acquired during an inpatient stay beginning with discharges on or after October 1, 2008.

- Similarly, the law now requires that the annual outpatient hospital PPS (OPPS) annual payment update be reduced by 2.0 percentage points for hospitals that do not meet certain quality reporting requirements. To receive the full OPPS annual payment update for services furnished in CY 2009, hospitals must report data in CY 2008 on seven quality measures that address emergency department or perioperative surgical care.

- As a VBP strategy for Medicare Part B services, CMS launched on July 1, 2007, the Physician Quality Reporting Initiative (PQRI). The PQRI provides a bonus for physicians and other health professionals who satisfactorily report on quality measures. CMS intends the PQRI to be a first step toward performance-based payment reform and public reporting of performance information for Part B providers.

- Home health agencies that submit the required quality data using OASIS receive payments based on the full home health market basket update. If a home health agency does not submit quality data, the home health market basket is reduced by 2 percentage points. The quality measures for each home health provider are reported on Home Health Compare.

- For End Stage Renal Disease (ESRD) services, as required by the Medicare Improvements for Patients and Providers Act, CMS will be developing a new ESRD bundled payment system for 2011 and a quality incentive program effective for 2012.

In addition, CMS has implemented a number of demonstration programs that support the further development and refinement of VBP initiatives. For example,

- Premier Hospital Quality Incentive Demonstration . Through the Premier Hospital Quality Incentive Demonstration CMS aims to see a significant improvement in the quality of inpatient care by awarding incentive payments to hospitals for high quality in several clinical areas (i.e., inpatients with: heart attack, heart failure, pneumonia, coronary artery bypass graft, and hip and knee replacements), and by reporting extensive quality data on the CMS web site. The demonstration involves a CMS partnership with Premier Inc., a nationwide organization of not-for-profit hospitals. For the top decile hospitals for a given diagnosis, the bonus is two percent of the Diagnosis Related Group (DRG) based prospective payment for the measured condition. Hospitals in the second decile are paid a bonus incentive of one percent of the DRG based prospective payment amount.

- The Physician Group Practice (PGP) Demonstration. The Physician Group Practice (PGP) Demonstration seeks to align incentives for physician groups to manage the overall care for patients, especially for beneficiaries with chronic illness, multiple co-morbidities and those near the end of life. The demonstration encourages physician groups to proactively coordinate beneficiaries' total heath care needs; provides incentives to physicians to provide services efficiently and effectively; rewards improvements and delivery of high quality care; and creates a framework to collaborate with providers to the advantage of Medicare beneficiaries. Because they will share in any financial savings that result from improving the quality and cost efficiency of care, the groups have incentives to use new care management strategies and electronic tools that, based on clinical evidence and patient data, improve patient outcomes and lower total medical costs. Performance payments are based upon both cost efficiency for generating savings and performance on 32 quality measures that are phased in during the demonstration.

Rulemaking Cycles of Medicare Payment Systems

Inpatient Prospective Payment System (Fiscal Year Cycle)

Rulemaking Phase	Approximate Timeframe
Proposed rule development	Fall/winter
Proposed rule publication	Late spring (April/May)
Comment period	Late spring - early summer
Final rule publication	On or about August 1
Final rule effective date	October 1

Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System (Calendar Year Cycle)

Rulemaking Phase	Approximate Timeframe
Proposed rule development	Winter/spring
Proposed rule publication	Summer (June/July)
Comment period	Late summer - early fall
Final rule publication	On or about November 1
Final rule effective date	January 1

Physician Fee Schedule including Part B Drugs (Calendar Year Cycle)

Rulemaking Phase	Approximate Timeframe
Proposed rule development	Winter/spring
Proposed rule publication	Summer (June/July)
Comment period	Late summer - early fall
Final rule publication	On or about November 1
Final rule effective date	January 1

Skilled Nursing Facility Prospective Payment System (Fiscal Year Cycle)

Rulemaking Phase	Approximate Timeframe
Proposed rule development	Fall/winter
Proposed rule publication	Late spring (April/May)
Comment period	Late spring - early summer
Final rule publication	On or about August 1
Final rule effective date	October 1

Inpatient Rehabilitation Facility Prospective Payment System (Fiscal Year Cycle)

Rulemaking Phase	Approximate Timeframe
Proposed rule development	Fall/winter
Proposed rule publication	Late spring (April/May)
Comment period	Late spring - early summer
Final rule publication	On or about August 1
Final rule effective date	October 1

Inpatient Psychiatric Facility Prospective Payment System (Rate Year Cycle)

Rulemaking Phase	Approximate Timeframe
Proposed rule development	Winter
Proposed rule publication	January
Comment period	Late winter
Final rule publication	On or about May 1
Final rule effective date	July 1

Home Health Agency Prospective Payment System (Calendar Year Cycle)

Rulemaking Phase	Approximate Timeframe
Proposed rule development	Winter/spring
Proposed rule publication	Summer (June/July)
Comment period	Late summer - early fall
Final rule publication	On or about November 1
Final rule effective date	January 1

Hospice Wage Index (Fiscal Year Cycle)

Rulemaking Phase	Approximate Timeframe
Proposed rule development	Fall/winter
Proposed rule publication	Late spring (April/May)
Comment period	Late spring - early summer
Final rule publication	On or about August 1
Final rule effective date	October 1