## **GLOSSARY**

<u>Admitting diagnosis</u> – For an inpatient admission, the condition identified by the physician at the time of the patient's admission requiring hospitalization. For an outpatient encounter, the patient's reason for the visit. Reported using ICD-9-CM diagnosis codes and entered at Form Locator 76 on the CMS-1450/UB-92 claim form.

Advance Beneficiary Notice (ABN) – A form that must be submitted to and signed by a beneficiary in advance of receiving a service explaining that Medicare will probably not cover the service consistent with Medicare program determinations. Under the ABN, the beneficiary is given the choice either to receive or decline the service. If the beneficiary decides to receive the service, s/he agrees to pay for the service if, in fact, a non-coverage determination is made on the claim. Services for which an ABN has been obtained may be billed using the appropriate CPT/HCPCS code for the service together with modifier "GA" indicating "waiver of liability on file." A beneficiary cannot be held financially responsible for services which are non-covered on reasonable and necessary grounds unless an ABN has been given and signed.

Ambulatory Payment Classification (APC) – Groupings which define the unit for payment under Medicare's hospital Outpatient Prospective Payment System (OPPS). Under the OPPS, procedures, drugs and devices reported using CPT/HCPCS codes are assigned to specific APC groups or are packaged into APC groups to which other items and services performed or provided at the same session are assigned. Services within each APC are intended to be similar clinically and to require similar resource use. Several CPT/HCPCS codes may be assigned to the same APC group. For example CPT codes 64612, 64613 and 64614 are all assigned to APC 0204 "Level I Nerve Injections."

Assignment – A transfer of a beneficiary's right to receive payment for a covered item or service to the physician or provider who provided the item or service. Payment for Medicare claims submitted under an assignment are made directly to the provider (less applicable coinsurance and deductibles). When payment is made from Medicare to the provider or physician under an assignment, the provider cannot seek payment from beneficiary (or anyone else) for any amount in excess of the applicable coinsurance or deductible.

Average sales price – Manufacturer-reported prices for drugs and biologicals comprising total sales in dollars divided by total number of units sold (excluding sales not reported under the Medicaid rebate program). ASP is reported on a quarterly basis by manufacturers. Beginning in 2005, CMS sets payment for drugs and biologicals under Medicare Part B in the physician's office and freestanding facility settings at 106-percent of manufacturer-reported ASP.

<u>Capitation</u> – A form of payment under managed care in which participating providers receive a fixed dollar amount per health plan member per month. Under capitation, the payment amount per patient is not related to the number or intensity of services provided to the patient.

<u>Carrier</u> – A type of regional Medicare contractor responsible for administering claims for non-institutional providers who provide items and services under Medicare Part B, such as physicians and freestanding diagnostic or treatment facilities. As most of the services administered by carriers are within the Part B scope of benefits, these contractors are sometimes referred to as Part B carriers. Under the **Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the MMA)**, the term carrier is being replaced by the term "**Medicare Administrative Contractor**." See also **Fiscal Intermediary**.

<u>Category III code</u> – A category of CPT code for emerging technology, services and procedures. Category III codes are alphanumeric comprising 4 digits followed by a letter. Category III CPT codes allow data collection to substantiate widespread usage or in the FDA approval process. Category III codes are released earlier in the CPT cycle than standard (Category I) codes and are implemented six months after they are released. Category III codes are not referred for determination of national relative value units.

<u>Centers for Medicare and Medicaid Services (CMS)</u> – The agency that administers the Medicare program and that administers the Medicaid program at the federal level. CMS is an agency of the U.S. Department of Health and Human Services(HHS). CMS was formerly known as the Health Care Financing Administration (HCFA).

<u>Charge compression</u> – A term used to describe hospital charging practices in which charges for items and services billed under a particular cost center are not marked up uniformly from cost to charge with relatively lower mark up of charges from cost for higher cost items compared with lower cost items. For example, if there is a fixed \$5 fee per filled prescription and a 20% mark-up of charge over cost above that fee, a \$.05 aspirin may be marked up to \$5.06 where a \$1,000 biological may be marked up to a \$1,205. The resulting ratio of costs-to-charges for the aspirin is .0099 while the ratio for the biological is .8299—i.e., a non-uniform mark-up of charges compressed at higher levels of cost.

<u>Chargemaster</u> – Hospital charging system that generates a pre-determined charge for each item and service provided by the hospital using hospital-specific codes for identifying items and services.

<u>Claim Forms</u> – Forms used by providers to submit charges to payers. There are two standard claims forms: (1) the <u>CMS-1450</u> (also called the Uniform Bill or <u>UB-92</u>), which is the institutional claim form (e.g., used by hospitals, skilled nursing facilities, home health agencies), and (2) the <u>CMS-1500</u> (also called the Health Insurance Claim Form), which is the non-institutional claim form (e.g., used by physicians, medical equipment suppliers, independent diagnostic testing facilities). The CMS-1450 is maintained by the National Uniform Billing Committee. The CMS-1500 is maintained by the National Uniform Claim Committee.

<u>CMS-1450</u> – The Uniform Bill or UB-92 used by institutions. See **Claim Forms**.

<u>CMS-1500</u> – The Health Insurance Claim Form used by physicians, freestanding facilities and other non-institutional billers. See **Claim Forms**.

<u>Coinsurance</u> – The portion of the allowed payment amount for items and services for which a patient (or supplemental payer) is responsible. Coinsurance involves a percentage of the payer's allowance (e.g., 20 percent). See also **copayment**.

<u>Column 1/Column 2 Edits</u> – Edits under the <u>Correct Coding Initiative</u> that identify pairs of CPT/HCPCS codes that should not be reported together. Column 1/column 2 edits formerly were called comprehensive/component edits and generally reflect pairs of services in which the column 1 service is a comprehensive service that includes the column 2 service. When a column 1 service is billed together with a paired column 2 service, Medicare will pay only for the column 1 service.

Competitive Acquisition Program – A new method for paying for drugs and biologicals covered under Medicare Part B in the physician's office and freestanding facility settings that was enacted as part of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) and is scheduled to begin in 2006. Under the Competitive Acquisition Program, physicians will elect whether to continue to purchase and bill for categories of Part B covered drugs or to obtain them from regional Competitive Acquisition Program contractors. When physicians elect to have certain categories of drugs provided by their regional Competitive Acquisition Contractors, the physicians will no longer be responsible for purchasing or billing for those drugs or biologicals.

Comprehensive Outpatient Rehabilitation Facility (CORF) – A facility which is primarily engaged in providing (by or under the supervision of physicians) diagnostic, therapeutic, and restorative services to outpatients for the rehabilitation of injured, disabled, or sick persons. CORFs provide at least the following services: (1) physicians' services rendered by physicians, who are available at the facility on a full- or part-time basis; (2) physical therapy; and (3) social or psychological services. Drugs and biologicals may be provided by CORFs. Drugs and biologicals provided by CORFs are paid under the same methods as drugs and biologicals furnished by physicians in their offices.

<u>Copayment</u> – The portion of an allowed or approved payment amount for items and services for which a patient (or supplemental payer is responsible. Copayment involves a fixed dollar amount (e.g., \$10). See also **coinsurance**.

<u>Correct Coding Initiative (CCI)</u> – Coding policies that specify pairs of codes which should not be reported together on Medicare claim forms. The CCI was designed to control improper coding that may lead to inappropriately increased payments. The CCI policies were developed based on the CPT coding manual, national and local policies and edits, coding guidelines developed by national societies, analysis of standard medical and surgical practice, and review of current coding practice. The CCI is maintained by a Medicare contractor—AdminaStar Federal. CCI edits apply in the physician's office and

freestanding facility settings and in the hospital outpatient setting. The hospital outpatient CCI edits are released separate from the physician office/freestanding facility edits and are generally one calendar quarter behind the physician office/freestanding facility edits. There are two types of CCI edits: **column 1/column 2 edits** and **mutually exclusive edits**. With either type of edit, when both codes in a pair are reported, Medicare will pay only for the first code in the pair. Some CCI edits are absolute—no exceptions permitted. In other cases, exceptions may be permitted for distinct procedural services reported using modifier -59 "distinct procedural service."

<u>Cost center</u> – A line item on a cost report representing a department to which expenses are allocated. Charges billed under revenue codes are assigned to corresponding cost centers for determining cost-to-charge ratios. For example, the cost center to which pharmacy expenses are allocated is 56 "drugs charged to patients."

<u>Cost-to-charge ratio</u> – A ratio determined by dividing allocated expenses (costs) by billed charges for a specific hospital cost center or for a whole hospital. For example, the cost-to-charge ratio for pharmacy is determined by dividing total costs allocated to cost center 56 "drugs charged to patients" by total charges from corresponding pharmacy revenue codes, such as 25x and 63x ("pharmacy").

<u>Covered entities</u> – A term under the <u>Health Insurance Portability and Accountability Act of 1996</u> privacy standards that refers to the entities which must comply with the privacy standards. Covered entities include: health care providers who transmit health information in electronic form in connection with covered transactions (e.g., claims submission), health plans and health care clearinghouses.

Current Procedural Terminology (CPT®1) Codes — CPT codes are five-digit codes with descriptors used to report medical, surgical, and diagnostic services and procedures performed by physicians and certain other health care providers (such as hospital outpatient departments). There are categories levels of CPT codes: (1) category I represent the regular CPT code set, (2) category II are supplemental tracking codes used for performance measurement, (3) category III codes are temporary codes for emerging technology, services and procedures. The copyright for the CPT codes is held by the American Medical Association, and the AMA's CPT Editorial Research and Development coordinates and maintains CPT. The CPT codes are approved by an independent Editorial Panel comprising representatives from professional societies and payers. The CPT Editorial Panel obtains recommendations on petitions for new or revised codes and nomenclature from the CPT Advisory Committee comprising representatives from nearly all major professional societies. See also Healthcare Common Procedure Code Set (HCPCS) and Category III codes.

<u>Deductible</u> – A threshold amount for which a beneficiary is responsible for covered services over a specified period of time before a payer's obligation to pay begins. For example, the annual deductible for Medicare Part B that is \$110 in 2005.

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<sup>&</sup>lt;sup>1</sup> CPT is a registered trademark of the American Medical Association.

<u>Diagnosis-Related Groups (DRGs)</u> – Groupings which define the unit for payment under Medicare's hospital inpatient **Prospective Payment System (PPS)**. The DRG payment is an all-inclusive payment covering all non-physician services provided to the patient during the inpatient admission (with a few exceptions). Under the inpatient PPS, each hospital inpatient stay is assigned to one of over 500 DRGs determined by the principal diagnosis code, code(s) for any major operating room procedures performed, secondary diagnosis codes describing recognized complications and comorbidities, age and discharge status. A relative weight is assigned to each DRG which is multiplied by a standardized payment amount for operating and capital to determine the payment rate for the DRG. Hospital-specific payments are determined by applying geographic adjustments and may include other adjustments depending upon teaching status and provision of care to the poor.

Evaluation and Management (E&M) Codes – CPT codes in the range of 99201 through 99499 that are used to report services performed as office visits, hospital visits, or consultations. Each code in this range identifies the place of service, the type of service, the level of service provided. The typical time required to provide the service is indicated for many E&M codes. There are guidelines for determining the level of service which is appropriate to bill. When evaluation and management services are performed on the same date as another service provided by the same provider to the same beneficiary, modifier -25 must be included on the claim to indicate that the E&M service was a "significant, separately identifiable evaluation and management service by the same physician on the same day of the procedure or other service" provided.

Explanation of (Medicare) Benefits (EOB/EOMB) – Forms used by payers (including Medicare) to notify patients of the actions taken on their claims for payment. EOBs/EOMBs for denied claims indicate the reasons for denial. An important function of the EOB/EOMB is to inform patients of their appeal rights if they do not agree with the determinations made on their claims (denied claims or reduced allowed payment amounts).

<u>Fee-for-Service</u> – A payment method under which providers receive payment for each service rendered. Fee for service payment is distinguished from **prospective payment systems** or **capitation** under which inclusive payment is made for an encounter, an admission or per patient-per month.

<u>Fiscal Intermediary</u> – A type of regional Medicare contractor that is responsible for administering claims submitted by institutional providers, such as hospitals and skilled nursing facilities. Because many of the services administered by fiscal intermediaries are under the Medicare Part A scope of benefits, fiscal intermediaries are sometimes referred to as "Part A intermediaries." Under the **Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA)**, the term fiscal intermediary is being replaced by the term "Medicare Administrative Contractor." See also **carrier**.

<u>Functional equivalence</u> – A payment policy under the Medicare hospital Outpatient Prospective Payment System's transitional pass-through for new drugs and biologicals

under which CMS determined that the new drug darbepoetin would not be eligible for pass-through payment status because it had the same biological mechanism and produced the same clinical result as the older drug epoetin. In the **Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA)**, Congress prohibited CMS from applying a functional equivalence standard again in the future.

<u>Geographic Practice Cost Indices</u> – Factors used to adjust component relative values of the Medicare Physician Fee Schedule for differences among geographic regions in costs. There are discrete GPCIs for work, practice expense and malpractice insurance expense for each geographic region. See also **Medicare Physician Fee Schedule** and **Resource-Based Relative Value Scale**.

Global Service – For those procedures that have technical and professional components under the Medicare Physician Fee Schedule, the global service comprises both the **technical** and **professional components** of the procedure. Physicians bill for a global service by reporting the CPT code for the procedure with no modifier. For example, if a physician performs a limited needle electromyography service in his/her office, then the physician may bill 95870 ("needle electromyography; limited study of muscles in one extremity or non-limb [axial] muscles [unilateral or bilateral], other than thoracic paraspinal, cranial nerve supplied muscles, or sphincters") with no modifier to indicate the global service.

Healthcare Common Procedure Coding System (HCPCS) Codes – A two-level coding system to report procedures, drugs and devices . Level I comprises the CPT code system by agreement between CMS and the AMA. Level II consists of national codes coordinated and maintained by CMS. Level II codes are adopted by a national panel comprising representatives from CMS, the national Blue Cross and Blue Shield Association and America's Health Insurance Plans (AHIP, formerly the Health Insurance Association of America [HIAA]). Drugs, biologicals and medical devices are reported using HCPCS Level II codes. For example, botulinum toxin type A is reported using code J0858 "botulinum toxin type A, per unit."

Health Insurance Portability and Accountability Act of 1996 (HIPAA) – A law that covers a number of areas, including requirements for development of standards for electronic health care transactions (e.g., claims transmission), privacy and security of identifiable health information. Final Rules addressing these areas have been published. Prominent among these are the privacy standards, which govern how protected health information may be used or disclosed by covered entities.

<u>Hospital Outpatient</u> – A patient receiving medical services who is registered as a hospital patient but has not been admitted to the medical care facility on an inpatient basis. The patient may receive services in a hospital outpatient department or an emergency department.

<u>Hospital Outpatient Prospective Payment System (HOPPS)</u> – See Outpatient Prospective Payment System.

## International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-

<u>9-CM</u>) – A coding system based upon the World Health Organization's International Classification of Diseases. The US system, ICD-9-CM comprises three volumes:

(1) Volume 1 comprises a tabular list of diseases, (2) Volume 2 comprises an index to the list of diseases and (3) Volume 3 comprises a listing of procedure codes together with the corresponding index. The tabular list of diseases comprises a hierarchical listing of codes that describe diseases, symptoms, conditions, problems, or complaints. ICD-9-CM diagnosis codes are required by payers to support the medical necessity of items or services provided. ICD-9-CM procedure codes are used to report major procedures. In the hospital inpatient setting, ICD-9-CM procedure codes are used to assign admissions with operating room procedures to the corresponding surgical DRGs. A newer US modification of ICD—ICD-10-CM has been developed but has not yet been implemented.

Incident to Physicians' Services – A term used to describe coverage for items and services not provided directly by a physician but related to services provided by a physician. Incident-to services may include items and services provided by nurses, nurse practitioners or physician assistants who are employed by or in a contractual relationship with a physician who bills for their services when provided incident-to the physician's own services. To be covered as an "incident-to" service, the service must be: (1) an integral, although incidental, part of the physician's professional service; (2) commonly rendered without charge, or included in the physician's bill; (3) of a type that is commonly furnished in a physician's office or clinic; and (4) furnished under the physician's direct personal supervision (the physician is in the office suite and immediately available to respond but need not be in the treatment room with the patient). Similar rules cover hospital outpatient services provided incident to physicians' services. Drugs and biologicals which are not usually self-administered by the patient are covered as incident-to services under the Medicare program.

Independent Diagnostic Testing Facility (IDTF) — An entity independent of a hospital or physician's office that provides the technical component of certain diagnostic testing services. Carriers determine whether an IDTF is qualified to perform the technical component of a specific diagnostic service. The IDTF must be able to provide the required level of physician supervision for the specific diagnostic test (general supervision [physician not required to be in the office], direct supervision [physician must be in the office suite and immediately available but not required to be in the procedure room], personal supervision [physician must be in the procedure room with the patient]).

<u>Inpatient</u> – A patient who is admitted for an overnight stay to a medical facility.

<u>Inherent reasonableness</u> – Regulation under which CMS or local contractors may decrease or increase payments if the payments that otherwise would be determined using Medicare payment rules and procedures are considered grossly excessive or deficient because the payment amounts are grossly higher or lower than the acquisition costs for the items or services. For the purposes of this regulation, CMS has determined that

payments are grossly excessive or deficient if the payments are at least 15-percent above or below those costs.

Least Costly Alternative (LCA) – A Medicare payment policy in which local contractors may set the payment rate for one item at the payment rate for another item that is less costly. To apply LCA, the local contractor must find that the less costly alternative is a medically appropriate and realistically feasible alternative pattern of care. LCA may be implemented as policy only through the Local Coverage Determination process. When a carrier revises an existing policy to include an LCA determination, the entire LCD must be posted, but only the new LCA determination is subject to comment. Less stringent evidence is required to support an LCA determination than other LCDs. The most common example of LCA policy applied to drugs or biologicals is in the payment for leuprolide.

<u>Limiting charge</u> – Under the Medicare Physician Fee Schedule, there is a limit on the actual charge permitted for claims submitted on an unassigned basis. The limit is set at 115-percent of the non-participating physician's allowed charge. As a non-participating physician's allowed charge is 95-percent of a participating physician's allowed charge, the limiting charge is 109.25-percent of the published fee schedule amount for participating physicians.

<u>Local Coverage Determination (LCD)</u> – Policy issued by local Medicare contractors on coverage requirements for an item or service. LCDs include only the reasonable and necessary limitations and conditions for coverage developed by the local contractor. The LCD may include lists of covered and non-covered ICD-9-CM diagnosis codes as well as a list of HCPCS codes identifying the items and services to which the LCD applies. LCDs do not include coding guidelines, which relate covered diagnosis codes to corresponding CPT procedure codes. The coding guidelines are published in separate, but parallel documents. LCDs may be appealed to Administrative Law Judges through a "review" process. See also **Local Medical Review Policy**.

<u>Local Medical Review Policy (LMRP)</u> – Policy issued by local Medicare contractors on coverage requirements for an item or service. LMRPs included benefit category, statutory exclusions, reasonable and necessary limitations and coding guidelines. LMRPs have been superseded by Local Coverage Determinations (LCDs). All LMRPs must be converted to LCDs by December 2005. See also **Local Coverage Determination**.

<u>Major Diagnostic Category (MDC)</u> – Under the Medicare inpatient Prospective Payment System, hospital admissions are assigned to a specific Major Diagnostic Category based upon the principal diagnosis. Each Major Diagnostic Category comprises several **Diagnosis Related Groups (DRGs)** to which admissions are assigned by considering the principal diagnosis, major operating room procedure, secondary diagnoses (if these represent recognized complications or comorbidities) age, and discharge status.

<u>Managed Care Organization</u> – Entities that provide or arrange for the provision of healthcare items and services in return for a premium. Managed care organizations can provide health care items and services directly through their own provider groups or hospitals (e.g., the Kaiser-Permanente model) or may arrange for other provider groups or hospitals to provide these services for a fee (e.g., MCO contracts with independent practice associations [IPAs] to provide physician services). MCO arrangements with providers may include capitated payments, prospective payments, discounted fee for service payments or some other payment method.

<u>Medicaid</u> – A joint federal and state program that provides medical assistance to eligible persons. Eligibility is determined based upon federal standards, but states have discretion to include or exclude certain groups. Categories of covered services are based upon federal law requirements. However, detailed rules and policies about coverage and payment for items and services under Medicaid are left to the states. The federal government's share of payments (the Federal Medical Assistance Percentage) varies from state to state based upon a specific federal formula.

<u>Medical Necessity</u> – One of the considerations for determining coverage for a specific item or service provided to a particular beneficiary. Under Medicare law, coverage is provided only for services, procedures, and/or items that are considered reasonable and necessary for the diagnosis and treatment of a disease or condition.

<u>Medicare</u> – The federal health insurance program for persons 65 years of age and older, certain younger persons with disabilities, and persons with end-stage renal disease.

<u>Medicare Administrative Contractor</u> – An entity that has an agreement with CMS to administer the Medicare program for providers in specific state(s) or region(s). Medicare carriers and fiscal intermediaries are two types of Medicare contractors. Under the **Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA)**, the term carrier and fiscal intermediary is being replaced by the term "Medicare Administrative Contractor."

<u>Medicare Advantage Program</u> – The scope of benefits provided under Medicare Part C as amended by the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). The Medicare Advantage Program includes the Medicare Advantage managed care plans and preferred provider organization plans.

<u>Medicare Coverage Advisory Committee (MCAC)</u> – A committee comprising external experts as members at-large together with consumer and industry (non-voting) representatives that advises the Medicare program on coverage of specific items and services for particular indications for use. The MCAC consider coverage issues on referral from CMS.

<u>Medicare Physician Fee Schedule (MPFS)</u> – Medicare payment method for most physician and freestanding facility services, which is updated annually. The Medicare Physician Fee schedule uses resource-based relative values assigned to CPT/HCPCS

procedure codes which yield payment rates when multiplied by a conversion factor. Medicare Physician Fee Schedule services are adjusted for geographic differences in physician compensation, practice expense input costs and malpractice insurance costs through **Geographic Practice Cost Indices**. The Medicare Physician Fee Schedule is adjusted annually. See also **Resource-Based Relative Value Scale**.

## Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA)

A law enacting major reforms to the Medicare program including the creation of an outpatient prescription drug benefit, changes to Medicare coverage procedures, and changes to the methods for determining payment for drugs and biologicals covered under Part B. See also Part D.

Modifiers – Two-character (numeric, alpha or alphanumeric) codes used with CPT or HCPCS Level II codes to indicate that a service or procedure performed by the reporting provider has been altered by some specific circumstance but not changed in its definition or code. Some examples of modifiers are –TC "technical component," -26 "professional component," -25 "significant, separately identifiable evaluation and management service by the same physician on the same day of the procedure or other service," -59 "distinct procedural service," LT "left side (used to identify procedures performed on the left side of the body" RT "right side (used to identify procedures performed on the right side of the body)" -50 "bilateral procedure" -51 "multiple procedures."

<u>Mutually Exclusive Codes</u> – Edits under the Correct Coding Initiative that identify pairs of CPT/HCPCS codes that should not be reported together because they could not reasonably be performed in the same session or on the same day. When two mutually exclusive codes are billed together, Medicare will pay only for the service in the first column of the mutually exclusive code pair.

National Coverage Determination (NCD) – A determination by CMS as to whether an item or service is or not reasonable and necessary for a particular indication for use. National coverage determinations are issued following a process where CMS's Coverage and Analysis Group researches the medical evidence regarding the use of the specific item or service for a particular indication, may or may not refer the issue for a technology assessment or consideration by the Medicare Coverage Advisory Committee (MCAC) and issues a draft decision memorandum for comment before the determination is finalized. National Coverage Determinations are binding on local Medicare contractors and Medicare Advantage plans (except that Medicare Advantage plans may elect to cover services that are non-covered under fee-for-service Medicare). National Coverage Determinations may be appealed to the Departmental Appeals Board through a specific "review" process.

National Drug Code (NDC) – A 10-digit number assigned by the U.S. Food and Drug Administration (FDA) that uniquely describes a product and its packaging. An NDC comprises three components: the labeler (manufacturer) code, product code, and package code. When used to report drugs to payers, an 11-digit NDC format is used: xxxxx-xxxxxxxx (5 digits for the labeler, 4 for the product, and 2 for the package style). The 11-digit

code is derived from the 10-digit FDA version by using leading zeroes, depending upon the specific format of the FDA's NDC code for the drug.

Orphan drug – A drug or biological intended for use in patients with a rare disease affecting less than 200,000 individuals in the US may be designated by the US Food and Drug Administration as an orphan drug. When an orphan-designated drug or biological is approved by the FDA, it is given a seven-year market exclusivity period during which time no other substantially similar drug or biological may be approved unless the drug or biological can prove that it is clinically superior. BOTOX® obtained FDA approval as an orphan drug for three indications: blepharospasm, strabismus and cervical dystonia.<sup>2</sup>

<u>Outpatient Prospective Payment System (OPPS)</u> – The Medicare payment system for most hospital outpatient services comprising **Ambulatory Payment Classification** groups. As a prospective payment system, Medicare pays a fixed amount for a specific service or group of services, which is determined in advance and does not vary based upon actual resource utilization.

<u>Part A</u> – Scope of Medicare benefits paid for out of the Hospital Insurance Trust Fund. Part A benefits include inpatient hospital, skilled nursing facility, hospice and some home health services.

<u>Part B</u> – Scope of Medicare benefits paid for out of the Supplementary Medical Insurance Trust Fund. Part B benefits include physicians' services, outpatient hospital services, durable medical equipment, clinical laboratory services, some home health services, physical and occupational therapy, **Comprehensive Outpatient Rehabilitation** Facility (CORF) services and certain other services. Drugs and biologicals not usually self-administered by the patient are items and services incident-to physicians services that are covered under Part B.

<u>Part C</u> – Scope of Medicare benefits under the <u>Medicare Advantage Program</u> (formerly called the Medicare +Choice program). Part C includes Medicare Advantage managed care plans and preferred provider organization plans.

<u>Part D</u> – Medicare's outpatient prescription drug benefits enacted under the <u>Medicare Prescription Drug</u>, <u>Improvement and Modernization Act of 2003 (MMA)</u>. Part D excludes otherwise covered drugs if payment for the such drugs as prescribed and

BOTOX® is indicated for the treatment of cervical dystonia in adults to decrease the severity of abnormal head position and neck pain associated with cervical dystonia.

<sup>&</sup>lt;sup>2</sup> The current package labeling includes the following indications for BOTOX®:

BOTOX® is indicated for the treatment of severe primary axillary hyperhidrosis that is inadequately managed with topical agents.

BOTOX® is indicated for the treatment of strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and above. The efficacy of BOTOX® treatment in deviations over 50 prism diopters, in restrictive strabismus, in Duane's syndrome with lateral rectus weakness, and in secondary strabismus caused by prior surgical overrecession of the antagonist has not been established. BOTOX® is ineffective in chronic paralytic strabismus except when used in conjunction with surgical repair to reduce antagonist contracture.

dispensed or administered with respect to an individual is available under **Part A** or **Part B** for that individual.

<u>Participating physician/supplier</u> – A physician or other Medicare supplier who signs an annual participation agreement under which the physician or supplier agrees to accept all Medicare claims on an assignment-related basis. Participating physicians are eligible to receive payment based upon the full **Medicare Physician Fee Schedule** rate for a covered service; non-participating physicians receive only 95-percent of the participating physician allowed rate.

Pass-through payments – Under the Medicare hospital Outpatient Prospective Payment System (OPPS), Medicare provides separate "transitional pass-through" payments to hospital outpatient departments for new drugs, biologicals and categories of medical devices. Beginning in 2005, payments for most drugs and biologicals eligible for transitional pass-through status will be paid at 106-percent of the average sales price. Pass-through status is maintained for at least two but no more than three years after which period the drugs, biologicals or medical devices are paid under the same rules as other non-pass-through items. Botulinum toxin type A was paid as a pass-through drug from August 2000 through December 2002.

<u>Principal diagnosis</u> – The condition established after study to be chiefly responsible for an inpatient admission. For outpatient encounters, the diagnosis chiefly responsible for the outpatient services received. Under the Medicare inpatient **Prospective Payment System**, the principal diagnosis code determines the major diagnostic category to which the admission is assigned and from which the specific **Diagnosis-Related Group** is determined. The Principal Diagnosis is reported on the **CMS-1450/UB-92** at Form Locator 67.

<u>Professional Component</u> – Many diagnostic procedures comprise three potentially reportable services: the technical component (all services except those provided by the physician), the professional component (physician services for supervision and interpretation) and the global service (all services including the technical component and professional components). Professional component services are billed using modifier -26 "professional component."

<u>Prospective Payment System (PPS)</u> – A generic term for a payment system in which a fixed payment amount, determined in advance, is paid for a specific group of items and services. The unit of service may be a hospital admission (e.g., the Medicare inpatient Prospective Payment System involving **Diagnosis Related Groups**) or an encounter (e.g., the Medicare hospital **Outpatient Prospective Payment System** involving **Ambulatory Payment Classification** groups). The term "Prospective Payment System" also may be used as a shorthand to refer to the Medicare inpatient Prospective Payment System.

<u>Protected Health Information</u> – Information that: (1) is created or received by a health care provider, health plan, employer, or health care clearinghouse, (2) relates to the past,

present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and (3) identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual. Protected health information includes such information maintained or transmitted in any medium. There are limited exceptions to this definition of protected health information that include certain types of educational records and employment records.

Resource-Based Relative Value Scale (RBRVS) – The Medicare Physician Fee Schedule uses the RBRVS, which comprises three component relative value units (RVUs): work, practice expense and malpractice insurance expense. Work RVU values reflect physician time, mental effort and judgment, technical skill and physical effort and psychological stress (related to adverse outcomes with serious consequences). Practice expense RVUs are based upon non-physician labor, equipment, supplies and overhead. Malpractice insurance expense RVUs are intended to reflect the cost of professional liability insurance (malpractice insurance expense). Each component RVU is multiplied by a locality-specific component Geographic Practice Cost Index and the result is summed to provide total RVUs which are then multiplied by a conversion factor to determine the Medicare Physician Fee Schedule allowed rate. When new codes are adopted, initial RVU determinations are considered interim for the first year and then are finalized. RVUs are eligible for refinement every five years.

<u>Revenue Codes</u> – Codes developed by the National Uniform Billing Committee (NUBC) that categorize hospital services by the departments to which revenues are posted. These departments generally correspond to the cost centers under which expenses are allocated. Medicare requires hospitals to report revenue codes on CMS-1450/UB-92 claim forms in Form Locator 42. Most separately payable drugs and biologicals that require HCPCS coding are reported under Revenue Code 636 "drugs requiring detailed coding."

<u>Superbill</u> – A paper form or a computer program containing all of the codes and procedures performed by a physician or clinic. Used as a form of communication between the physician and billing staff who use the information on the superbill to complete standardized claim forms.

<u>Technical Component</u> – Many diagnostic procedures comprise three potentially reportable services: the technical component (all services except those provided by the physician), the professional component (physician services for supervision and interpretation) and the global service (all services including the technical component and professional components). Technical component services are billed using modifier –TC "technical component."

<u>Uniform Bill-92 (UB-92)</u> – Institutional claim form also called the **CMS-1450**. See Claim Forms.

Widely Available Market Price (WAMP) – Price that a prudent physician or supplier would pay for the drug or biological. The WAMP is determined by the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) through studies, which may include surveys. In determining such price, the OIG shall take into account the discounts, rebates, and other price concessions routinely made available to such prudent physicians or suppliers for such drugs or biologicals. In determining the WAMP, the OIG shall consider information from one or more of the following sources: (1) manufacturers, (2) wholesalers, (3) distributors, (4) physician supply houses, (5) specialty pharmacies, (6) group purchasing arrangements, (7) surveys of physicians, (8) surveys of suppliers, (9) information on such market prices from insurers and (10) information on such market prices from private health plans. If the WAMP exceeds the average sales price (ASP) by a threshold percentage (which for 2005 is 5-percent), CMS may disregard that ASP and set the payment at the WAMP.