Appendix J.—Glossary of Acronyms and Terms

Glossary of Acronyms

AAMI — Association for the Advancement of Medical Instrumentation
AART — American Association of Respiratory Therapists
ACRS — Accelerated Cost Recovery System
AFNOR — Association Francaise de Normalisation
ANSI — American National Standards Institute, Inc.
AOA — American Osteopathic Association
ASTM — American Society for Testing and Materials
BMD — Bureau of Medical Devices (Canada)
BSI — British Standards Institution
CABG — coronary artery bypass graft
CAPD — continuous ambulatory peritoneal dialysis
CCCN — Customs Cooperation Council Nomenclature
CDC – Centers for Disease Control (PHS)
CEN — European Committee for Standardization
CENELEC — European Committee for Electrotechnical Standardization
CFR — Code of Federal Regulations
CHAMPUS — Civilian Health and Medical Program of the Uniformed Services
CID — commercial item description
CLIA — Clinical Laboratory Improvement Act
CLMA — Contact Lens Manufacturers Association
CON — Certificate of need
CPR — customary, prevailing, and reasonable
CSA — Canadian Standards Association
CT — computed tomography
DEN – Device Experience Network (FDA)
DHHS — Department of Health and Human Services
DHSS — Department of Health and Social Security (United Kingdom)
DIN — Deutsches Institut fur Normung
DISC — Domestic International Sales Corp.
DME — durable medical equipment
DOC — Department of Commerce
DRGs — diagnosis related groups
ERTA — Economic Recovery Tax Act of 1981
ESRD — end-stage renal disease
FDA — Food and Drug Administration (PHS, DHHS)
GAO – General Accounting Office (U.S. Congress)
GATT — General Agreement on Tariffs and Trade
HCFA -- Health Care Financing Administration (DHHS)
HIDI — Health-Care Instrument and Device Institute
HIMA — Health Industry Manufacturers' Association
HMO — health maintenance organization
IDE — investigational device exemption
IEC — International Electrotechnical Commission
IFAC — Industry Functional Advisory Committee (DOC)
IND — investigational new drug
IV — intravenous
IPA — individual practice association
IPPB — intermittent positive pressure breathing
IRS — Internal Revenue Service
ISO — International Organization for Standardization
ITA — International Trade Administration (DOC)
IUD — intrauterine device
JCAH — Joint Commission on Accreditation of Hospitals
JIS – Japanese Industrial Standards
MEDIPP — Medical District Initiated Program Planning
MITI — Ministry of International Trade and Industry (Japan)
NBS — National Bureau of Standards (DOC)
NCCLS — National Committee on Clinical Laboratory Standards
NCI – National Cancer Institute (NIH)
NFPA — National Fire Protection Association
NHLBI — National Heart, Lung, and Blood Institute (NIH)
NHS — National Health Service (United Kingdom)
NIADDK — National Institute of Arthritis, Diabetes, Digestive, and Kidney Diseases (NIH)
NIH – National Institutes of Health (PHS, DHHS)

NMR	– nuclear magnetic resonance
NSF	– National Science Foundation
OEA	– Office of Export Administration (DOC)
OHTA	– Office of Health Technology (PHS, DHHS)
OIML	– International Organization for Legal Metrology
OMB	– Office of Management and Budget
OTA	— Office of Technology Assessment (U.S. Congress)
PHS	– Public Health Service, DHHS
PMAA	– premarket approval application
PRO	— peer review organization
PSRO	– Professional Standards Review Organization
R&D	research and development
Rehab R&D	- Rehabilitation Research and Development
SBIC	— Small Business Investment Corp.
SBIR	— Small Business Innovation Research
SIC	— Standard Industrial Classification
TEFRA	— Tax Equity and Fiscal Responsibility Act of 1982
TÜV	— Technischer Uberwachungs Verein
UCR	— usual, customary, and reasonable charges
UL	— Underwriters Laboratories, Inc.
U.S.C.	— United States Code
USTR	— U.S. Trade Representative
VA	— Veterans Administration
VAMKC	— Veterans Administration Marketing Center
VAREC	— Veterans Administration Rehabilitation Engineering Center
VAT	— value added tax
VDE	— Verband Deutscher Elektrotechniker
WHO	— World Health Organization
YAG	— yttrium aluminum garnet

Glossary of Terms

Applied research: Investigation whose objective is to gain knowledge or understanding necessary for determining the means by which a recognized and specific need may be met.

Basic research: Original investigation whose objective is to gain fuller knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications in mind.

Capital costs: Expenditures for plant and equipment used in providing a service. Under Medicare's prospective hospital payment system established by the Social Security Amendments of 1983 (Public Law 98-21), hospitals' capital costs (depreciation, interest, and return on equity to for-profit institutions) are treated as passthroughs (i. e., are not subject to the new system's controls).

Certificate of need (CON): A State regulatory planning mechanism encouraged by the National Health Planning and Resources Development Act (Public Law 93-641) to control expenditures for and distribution of expensive medical care facilities and equipment. CON applications are reviewed by local health systems agencies, which recommend approval or disapproval to State health planning agencies.

Class 1: One of three regulatory classes set up by the 1976 Medical Device Amendments (Public Law 94-295). Class I, general controls, contains devices for which general controls authorized by the act are sufficient to provide reasonable assurances of safety and effectiveness. Manufacturers of Class I devices must register their establishments and list their devices with the Food and Drug Administration (FDA), notify FDA before marketing a device, and conform to good manufacturing practices.

Class II: The regulatory class of devices for which general controls are considered insufficient to assure safety and effectiveness and information exists to establish performance standards.

Class III: The regulatory class of devices for which Class I general controls are insufficient to ensure safety and effectiveness, information does not exist to establish performance standards, *and* the device supports life, prevents health impairment, or presents a potentially unreasonable risk of illness or injury.

Conditions of participation: Requirements that a provider must meet in order to be allowed to receive payments for Medicare patients. An example is the requirement that hospitals conduct utilization review.

Development: Systematic use of the knowledge or understanding gained from research in the design and development of prototypes and processes.

Device type: All products of a particular type or a grouping of separate types of devices that are similar, as categorized by FDA. FDA has classified device types according to the potential risk posed by their use and the degree of regulation required.

Diagnosis related groups (DRGs): Groupings of diagnostic categories drawn from the International Classification of Diseases and modified by the presence of a surgical procedure, patient age, presence or absence of significant comorbidities or complica-

tions, and other relevant criteria. DRGs are the case-mix measure mandated for Medicare's prospective hospital payment system by the Social Security Amendments of 1983 (Public Law 98-21).

DRG payment: The system of prospective payment for inpatient services by Medicare which was mandated by the Social Security Amendments of 1983.

Good manufacturing practices: Requirements regarding the manufacturing, packing, storage, and installation of devices required under the Medical Device Amendments of 1976 and applicable to all three regulatory classes of devices.

Investigational device exemption (IDE): A regulatory category and process under which FDA permits limited use of an unapproved medical device in controlled settings for the purpose of collecting data on safety and effectiveness. This information may subsequently be used in support of a premarketing approval application.

Medical device: Any instrument, apparatus, or similar or related article that is intended to prevent, diagnose, mitigate, or treat disease or to affect the structure or function of the body.

Medical technology: The drugs, devices, and medical and surgical procedures used in medical care, and the organizational and support systems within which such care is provided.

Nuclear magnetic resonance (NMR) imaging: A diagnostic imaging modality that uses radiowaves and powerful magnetic fields rather than ionizing radiation.

Orphan product: Defined by the Orphan Drug Act of 1983 (Public Law 97-414) as drugs and medical devices for rare diseases or conditions.

Peer review organizations (PROS): Physician organizations established by the Tax Equity and Fiscal Responsibility Act of 1982 (Public Law *97-248)* to replace Professional Standards Review Organizations. Hospitals are mandated to contract with PROS to review quality of care and appropriateness of admissions and readmissions. PROS are also termed utilization and quality control peer review organizations.

Postamendments device: A medical device first marketed after May 1, *1976,* when the Medical Device Amendments took effect.

Preamendments device: A medical device marketed before May 1, *1976,* when the Medical Device Amendments took effect.

Premarket approval application (PMAA): An application to FDA for approval to market a new device. The sponsor of the device must submit to FDA information to document its safety and effectiveness before the drug may be marketed.

Procedure (medical or surgical): A medical technology involving any combination of drugs, devices, and provider skills and abilities. Appendectomy, for example, may involve at least drugs (for anesthesia), monitoring devices, surgical devices, and the skilled actions of physicians, nurses, and support staff.

Professional Standards Review Organizations (PSROs): Community-based, physician-directed, nonprofit agencies established under the Social Security Amendments of 1972 (Public Law *92-603)* to monitor the quality and appropriateness of institutional health care provided to Medicare and Medicaid beneficiaries.

Prospective payment: Payment for medical care on the basis of rates set in advance of the time period in which they apply. The unit of payment may vary from individual medical services to broader categories, such as hospital case, episode of illness, or person (cavitation).

Standard Industrial Classification (SIC) codes: A categorization of data on products and companies that is used by the U.S. Department of Commerce. Establishments (plants) are assigned to SIC "industries" on the basis of their primary line of business. However, SIC data on shipments of a specific product include all shipments of the relevant product, regardless of the "industry" in which the producing establishment is classified.

Substantially equivalent device: A device first marketed after the *1976* Medical Device Amendments that FDA has found to be similar to a device already being marketed. To be found substantially equivalent, a postamendments device need not be identical to a preamendments device, but must not differ markedly in materials, design, or energy source.

Third-party payment: Payment by a private insurer or government program to a medical provider for care given to a patient.

Transitional devices: Devices that were regulated as new drugs before enactment of the 1976 Medical Device Amendments.