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Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, et al.
Medicare Program; Revisions to Payment Policies, etc.; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 414, 415, and 424

[CMS–1321–FC and CMS–1317–F]

RINs 0938–AO24 and 0938–AO11

Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; Revisions to the Payment Policies of Ambulance Services Under the Fee Schedule for Ambulance Services; and Ambulance Inflation Factor Update for CY 2007

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period addresses certain provisions of the Deficit Reduction Act of 2005, as well as making other changes to Medicare Part B payment policy. These changes are intended to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services. This final rule with comment period also discusses geographic practice cost indices (GPCI) changes; requests for additions to the list of telehealth services; payment for covered outpatient drugs and biologicals; payment for renal dialysis services; policies related to private contracts and opt-out; policies related to bone mass measurement (BMM) services, independent diagnostic testing facilities (IDTFs), the physician self-referral prohibition; laboratory billing for the technical component (TC) of physician pathology services; the clinical laboratory fee schedule; certification of advanced practice nurses; health information technology, the health care information transparency initiative; updates the list of certain services subject to the physician self-referral prohibitions, finalizes ASP reporting requirements, and codifies Medicare's longstanding policy that payment of bad debts associated with services paid under a fee schedule/charge-based system are not allowable.

We are also finalizing the calendar year (CY) 2006 interim RVUs and are issuing interim RVUs for new and revised procedure codes for CY 2007.

In addition, this rule includes revisions to payment policies under the fee schedule for ambulance services and the ambulance inflation factor update for CY 2007.

As required by the statute, we are announcing that the physician fee schedule update for CY 2007 is −5.0 percent, the initial estimate for the sustainable growth rate for CY 2007 is 2.0 percent and the CF for CY 2007 is $35.9848.

DATES: *Effective Date:* These regulations are effective on January 1, 2007.

Comment Date: Comments will be considered if we receive them at one of the addresses provided below, no later than 5 p.m. on January 2, 2007.

ADDRESSES: In commenting, please refer to file code CMS–1321–FC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/eRulemaking.* Click on the link ''Submit electronic comments on CMS regulations with an open comment period.'' (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1321–FC, P.O. Box 8014, Baltimore, MD 21244–8014.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1321–FC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7197 in advance to schedule your arrival with one of our staff members.

Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the ''Collection of Information Requirements'' section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Pam West, (410) 786–2302 (for issues related to practice expense).

Stephanie Monroe, (410) 786–6864 (for issues related to the geographic practice cost index).

Craig Dobyski, (410) 786–4584 (for issues related to list of telehealth services).

Roberta Epps, (410) 786–4503 (for issues related to diagnostic imaging services).

Bill Larson, (410) 786–4639 (for issues related to coverage of bone mass measurement and addition of ultrasound screening for abdominal aortic aneurysm to the ''Welcome to Medicare'' benefit).

Dorothy Shannon, (410) 786–3396 (for issues related to the outpatient therapy cap).

Catherine Jansto, (410) 786–7762 (for issues related to payment for covered outpatient drugs and biologicals).

Henry Richter, (410) 786–4562 (for issues related to payments for end-stage renal disease facilities).

Fred Grabau, (410) 786–0206 (for issues related to private contracts and opt-out provision).

David Walczak, (410) 786–4475 (for issues related to reassignment provisions).

August Nemec, (410) 786–0612 (for issues related to independent diagnostic testing facilities).

Anita Greenberg, (410) 786–4601 (for issues related to the clinical laboratory fee schedule).

James Menas, (410) 786–4507 (for issues related to payment for physician pathology services).

Anne Tayloe, (410) 786–4546; or

In addition, because of the many organizations and terms to which we refer by acronym in this final rule with comment period, we are listing these acronyms and their corresponding terms in alphabetical order below:

AAA Abdominal aortic aneurysm
AAD American Academy of Dermatology
AAFP American Academy of Family Physicians
AANS American Association of Neurological Surgeons
AAO American Academy of Ophthalmology
AAOS American Academy of Orthopaedic Surgeons
AATS American Association for Thoracic Surgery
ACC American College of Cardiology
ACG American College of Gastroenterology
ACHPN Advanced Certified Hospice and Palliative Nurse
ACOG American College of Obstetrics and Gynecology
ACR American College of Radiology
ACS American College of Surgeons
ADA American Dietetic Association
AFROC Association of Freestanding Radiation Oncology Centers
AGA American Gastroenterological Association
AMA American Medical Association
AMP Average manufacturer price
APC Ambulatory payment classification
ASA American Society of Anesthesiologists
ASC Ambulatory surgical center
ASCRS American Society of Colon and Rectal Surgeons
ASGE American Society of Gastrointestinal Endoscopy
ASP Average sales price
ASSH American Society for Surgery of the Hand
ASTRO American Society for Therapeutic Radiology and Oncology
AUA American Urological Association
BBA Balanced Budget Act of 1997 (Pub. L. 105–33)
BBRA [Medicare, Medicaid and State Child Health Insurance Program] Balanced Budget Refinement Act of 1999 (Pub. L. 106–113)

BIPA Medicare, Medicaid, and SCHIP Benefits Improvement Protection Act of 2000
BLS Bureau of Labor Statistics
BMD Bone mineral density
BMM Bone mass measurement
BN Budget neutrality
BNF Budget neutrality factor
BP Best price
CAD Computer-aided detection
CAH Critical access hospital
CAP Competitive acquisition program
CBSA Core-Based Statistical Area
CCI Correct Coding Initiative
CEO Chief executive officer
CF Conversion factor
CFO Chief financial officer
CFR Code of Federal Regulations
CMP Competitive medical plan
CMS Centers for Medicare & Medicaid Services
CNS Clinical nurse specialist
CPI Consumer Price Index
CPT (Physicians') Current Procedural Terminology (4th Edition, 2002, copyrighted by the American Medical Association)
CT Computed tomography
CTA Computed tomographic angiography
CY Calendar year
DHS Designated health services
DME Durable medical equipment
DMEPOS Durable medical equipment, prosthetics, orthotics, and supplies
DRA Deficit Reduction Act
DSMT Diabetes outpatient self-management training services
DXA Dual energy x-ray absorptiometry
E/M Evaluation and management
EPO Erythopoeitin
ESRD End stage renal disease
FAX Facsimile
FDA Food and Drug Administration (HHS)
FQHC Federally qualified health center
FR **Federal Register**
GAF Geographic adjustment factor
GAO Government Accountability Office
GDP Gross domestic product
GPO Group purchasing organization
GPCI Geographic practice cost index
HCPAC Health Care Professional Advisory Committee
HCPCS Healthcare Common Procedure Coding System
HCRIS Healthcare Cost Report Information System
HSA Health Savings Account
HHA Home health agency
HHS [Department of] Health and Human Services
HIT Health information technology
HMO Health maintenance organization
HOCM High osmolar contrast media
HPSA Health Professional Shortage Area
HRSA Health Resources Services Administration (HHS)
HUD [Department of] Housing and Urban Development
ICF Intermediate care facilities
IDTF Independent diagnostic testing facility
IFC Interim final rule with comment period
IPPE Initial preventive physical examination
IPPS Inpatient prospective payment system
IVIG Intravenous immune globulin
IWPUT Intra-service work per unit of time
JCAAI Joint Council of Allergy, Asthma, and Immunology
LCD Local coverage determination
LOCM Low osmolar contrast media
LOINC Logical Observation Identifiers Names and Codes
MA Medicare Advantage
MCP Monthly capitation payment
MedPAC Medicare Payment Advisory Commission
MEI Medicare Economic Index
MLN Medicare Learning Network
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173)
MNT Medical nutrition therapy
MRA Magnetic resonance angiography
MRI Magnetic resonance imaging
MSA Metropolitan statistical area
MSVP Multi-specialty visit package
NCD National coverage determination
NCQDIS National Coalition of Quality Diagnostic Imaging Services
NDC National drug code
NEMA National Electrical Manufacturers Association
NHE National health expenditures
NOP National Osteoporosis Foundation
NP Nurse practitioner
NPP Nonphysician practitioners
NPWP Nonphysician Work Pool
NSQIP National Surgical Quality Improvement Program
OBRA Omnibus Budget Reconciliation Act
OIG Office of Inspector General
OMB Office of Management and Budget
OPD Outpatient Department
OPPS Outpatient prospective payment system
OSCAR Online Survey and Certification and Reporting
PA Physician assistant
PBM Pharmacy benefit managers
PC Professional component
PE Practice Expense
PE/HR Practice expense per hour
PEAC Practice Expense Advisory Committee
PERC Practice Expense Review Committee
PET Positron emission tomography
PFS Physician Fee Schedule
PLI Professional liability insurance
PPI Producer price index
PPO Preferred provider organization
PPS Prospective payment system
PRA Paperwork Reduction Act
PRM Provider Reimbursement Manual
PT Physical therapy
QCT Quantitative computerized tomography
RFA Regulatory Flexibility Act
RHC Rural health clinic
RIA Regulatory impact analysis
RN Registered nurse
RUC [AMA's Specialty Society] Relative (Value) Update Committee
RVU Relative value unit
SGR Sustainable growth rate
SMS [AMA's] Socioeconomic Monitoring System
SNF Skilled nursing facility
SNM Society for Nuclear Medicine
SPA Single photon absorptiometry
STS Society of Thoracic Surgeons
SVS Society for Vascular Surgery
SXA Single energy x-ray absorptiometry
TA Technology Assessment
TC Technical Component
UAF Update adjustment factor
UPIN Unique Physician Identification Number
USPSTF United States Preventive Services Task Force
VA [Department of] Veteran Affairs
WAC Wholesale acquisition cost
WAMP Widely available market price
WHO World Health Organization

I. Background

Since January 1, 1992, Medicare has paid for physicians' services under section 1848 of the Social Security Act (the Act), ''Payment for Physicians' Services.'' The Act requires that payments under the physician fee schedule (PFS) be based on national uniform relative value units (RVUs) based on the resources used in furnishing a service. Section 1848(c) of the Act requires that national RVUs be established for physician work, practice expense (PE), and malpractice expense. Before the establishment of the resource-based relative value system, Medicare payment for physicians' services was based on reasonable charges.

A. Development of the Relative Value System

1. Work RVUs

The concepts and methodology underlying the PFS were enacted as part of the Omnibus Budget Reconciliation Act (OBRA) of 1989 (Pub. L. 101–239), and OBRA 1990 (Pub. L. 101–508). The final rule, published November 25, 1991 (56 FR 59502), set forth the fee schedule for payment for physicians' services beginning January 1, 1992. Initially, only the physician work RVUs were resource-based, and the PE and malpractice RVUs were based on average allowable charges.

The physician work RVUs established for the implementation of the fee schedule in January 1992 were developed with extensive input from the physician community. A research team at the Harvard School of Public Health developed the original physician work RVUs for most codes in a cooperative agreement with the Department of Health and Human Services (HHS). In constructing the code-specific vignettes for the original physician work RVUs, Harvard worked with panels of experts, both inside and outside the Federal government, and obtained input from numerous physician specialty groups.

Section 1848(b)(2)(A) of the Act specifies that the RVUs for radiology services are based on relative value scale we adopted under section

Response: We recognize that comparing groups of physicians by price and quality measures could be useful both for consumers and patients in regions where these groups are widely available. We also appreciate the usefulness of the data for internal quality improvement for physician groups. However, for purposes of consumer choice, it may be important to have physician-specific information. Even with a group, beneficiaries would want to know the physician's treatment patterns, including quality information, to best suit the beneficiary's needs or preferences. We agree that information on both price and quality on individual physicians would be useful for consumers and patients.

S. Bad Debt Payment for Services Associated With Reasonable Charge/Fee Schedules

Under the Medicare program, payment may be made for unrecovered costs (bad debt) attributable to uncollectible deductible and coinsurance of Medicare beneficiaries as specified in § 413.89 and the Provider Reimbursement Manual (PRM) (CMS Pub. 15 Part 1, Chapter 3). Entities currently eligible to receive Medicare bad debt payments, with some limitations, include hospitals, skilled nursing facilities (SNFs), CAHs, RHCs, ESRD facilities, FQHCs, community mental health clinics, health maintenance organizations (HMOs) reimbursed on a cost basis, competitive medical plans (CMPs), and health care pre-payment plans. The bad debt policy for ESRD facilities is set forth in § 413.178.

The current bad debt regulation at § 413.89(i) excludes payment of bad debts specifically for those services furnished by anesthetists paid under a fee schedule. In the February 10, 2003 **Federal Register**, we published the Provider Bad Debt Payment proposed rule where we proposed to amend the language in the existing bad debt regulations to clarify that bad debts are not recognized or reimbursed for all covered services paid for under a reasonable charge-based methodology or a fee schedule (68 FR 6682). As stated in that proposed rule, the proposed amendment was intended to clarify our longstanding policy and is not a change in policy.

In this final rule with comment period, we are finalizing the amendment to the regulations, as proposed in the February 10, 2003 proposed rule, to clarify that payment of bad debts for covered services paid for under a reasonable charge-based methodology or a fee schedule is not allowable. In the February 10, 2006 **Federal Register** (71 FR 6991), we issued a notice extending the timeline for publication of a final rule associated with provisions of the February 10, 2003 proposed rule by one year to February 10, 2007. At this time, we are not finalizing other proposed provisions of the February 10, 2003 proposed rule.

We received the following comment regarding this provision from the February 10, 2003 proposed rule.

Comment: A commenter stated that the clarification of policy that bad debt reimbursement is not available for services paid under a fee schedule is a change in policy for outpatient therapy.

Response: During the initial stages of developing the Medicare program in 1966, the issue of ''bad debt'' arose but was not mentioned explicitly in the statute. However, at that time, based on the intent of the anti-cross-subsidization principle found in the definition of ''reasonable cost'' at section 1861(v)(1)(A) of the Act, Medicare adopted the policy to pay for the *unrecovered costs* attributable to uncollectible deductible and coinsurance of Medicare beneficiaries. Accordingly, we believe that this statutory prohibition on cross-subsidization does not apply where services are reimbursed on anything other than the basis of ''reasonable costs''.

The Medicare program has never allowed payment of bad debts for services paid for on the basis of a fee schedule or reasonable charge methodology, such as but not limited to, services of physicians, suppliers, certified registered nurse anesthetists, or NPs. Under a fee schedule or reasonable charge methodology, Medicare does not share proportionately in an entity's incurred costs but rather makes payment for a specific service. The payment is not related to the cost of a service and thus, does not embody the concept of unrecovered costs due to uncollected amounts of deductibles and coinsurance. Thus, payment of bad debt applies only to services reimbursed on the basis of reasonable cost or to services paid under one of Medicare's prospective payment systems that have a basis in reasonable costs that do not reflect Medicare payment of bad debts during a specified provider base period. Accordingly, when outpatient therapy services began to be paid for on a fee schedule methodology, payment of bad debts associated with these services was no longer available.

Therefore, we do not agree with the commenter and we are revising § 413.89(i) and adding new § 413.178(d) as proposed.

III. Revisions to the Payment Policies of Ambulance Services under the Fee Schedule for Ambulance Services and the Ambulance Inflation Factor Update for CY 2007.

Under the ambulance fee schedule, the Medicare program pays for transportation services for Medicare beneficiaries when other means of transportation are contraindicated. Ambulance services are classified into different levels of ground (including water) and air ambulance services based on the medically necessary treatment provided during transport. These services include the following levels of service:

- For Ground—
  + Basic Life Support (BLS)
  + Advanced Life Support, Level 1 (ALS1)
  + Advanced Life Support, Level 2 (ALS2)
  + Specialty Care Transport (SCT)
  + Paramedic ALS Intercept (PI)
- For Air—
  + Fixed Wing Air Ambulance (FW)
  + Rotary Wing Air Ambulance (RW)

A. History of Medicare Ambulance Services

1. Statutory Coverage of Ambulance Services

Under sections 1834(l) and 1861(s)(7) of the Social Security Act (the Act), Medicare Part B (Supplemental Medical Insurance) covers and pays for ambulance services, to the extent prescribed in regulations, when the use of other methods of transportation would be contraindicated by the beneficiary's medical condition.

The House Ways and Means Committee and Senate Finance Committee Reports that accompanied the 1965 Social Security Amendments suggest that the Congress intended that—

- The ambulance benefit cover transportation services only if other means of transportation are contraindicated by the beneficiary's medical condition; and
- Only ambulance service to local facilities be covered unless necessary services are not available locally, in which case, transportation to the nearest facility furnishing those services is covered (H.R. Rep. No. 213, 89th Cong., 1st Sess. 37 and Rep. No. 404, 89th Cong., 1st Sess. Pt 1, 43 (1965)).

The reports indicate that transportation may also be provided from one hospital to another, to the beneficiary's home, or to an extended care facility.

2. Medicare Regulations for Ambulance Services

Our regulations relating to ambulance services are set forth at 42 CFR part 410, subpart B and 42 CFR part 414, subpart H. Section 410.10(i) lists ambulance services as one of the covered medical and other health services under Medicare Part B. Therefore, ambulance services are subject to basic conditions and limitations set forth at § 410.12 and to specific conditions and limitations included at § 410.40. Part 414, subpart H, describes how payment is made for ambulance services covered by Medicare.

The national fee schedule for ambulance services is being phased in over a 5-year transition period beginning April 1, 2002 as specified in § 414.615. As of January 1, 2006, the total payment amount for air ambulance providers and suppliers is based on 100 percent of the national ambulance fee schedule. In accordance with section 414 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108–173), we added § 414.617 which specifies that for ambulance services furnished during the period July 1, 2004 through December 31, 2009, the ground ambulance base rate is subject to a floor amount, which is determined by establishing nine fee schedules based on each of the nine census divisions, and using the same methodology as was used to establish the national fee schedule. If the regional fee schedule methodology for a given census division results in an amount that is lower than or equal to the national ground base rate, then it is not used, and the national fee schedule amount applies for all providers and suppliers in the census division. If the regional fee schedule methodology for a given census division results in an amount that is greater than the national ground base rate, then the fee schedule portion of the base rate for that census division is equal to a blend of the national rate and the regional rate. For CY 2006, this blend is 40 percent regional ground base rate and 60 percent national ground base rate. As of January 1, 2007, the total payment amount for ground ambulance providers and suppliers will be based on either 100 percent of the national ambulance fee schedule or 80 percent of the national ambulance fee schedule and 20 percent of the regional ambulance fee schedule.

B. Provisions of the Final Regulation

In this rule, we are finalizing changes to the fee schedule for payment of ambulance services by adopting revised geographic designations for urban and rural areas as set forth in OMB's Core-Based Statistical Areas (CBSAs) standard. We are adding the definition of ''urban area'' as defined by the Executive Office of Management and Budget (OMB). In addition, we are removing the definition of ''Goldsmith modification'' and amending our definition of ''rural area'' to include areas determined to be rural under the most recent version of the Goldsmith modification.

We are withdrawing our proposal to change the language of our regulation defining ''specialty care transport (SCT)'' to conform to our existing payment policies. In response to public comments, we are broadening and clarifying our interpretation of the existing language and responding to other issues associated with the definition of SCT.

In addition, we are discontinuing our annual review of the original CF assumptions and of the original air ambulance rates from the initial implementation of the fee schedule in 2002 because we have not identified any significant differences from those assumptions in the 4 years since the implementation of the fee schedule. We will continue to monitor payment and billing data on an ongoing basis and make adjustments to the CF and to air ambulance rates as appropriate to reflect any significant changes in these data.

Finally, in response to public comment, we are withdrawing our proposal to revise our current definition of ''Emergency response'' to further specify the conditions that warrant a higher payment for immediate response. Our reasons for withdrawing our proposal are explained in section III.B.4. of this preamble.

1. Adoption of New Geographic Standards for the Ambulance Fee Schedule

Historically, the Medicare ambulance fee schedule has used the same geographic area designations as the acute care hospital IPPS and other Medicare payment systems to take into account appropriate urban and rural differences. This provides a consistent and objective national definition for ambulance payment purposes within the ambulance fee schedule and generally across Medicare payment systems. It also utilizes geographic area designations that more realistically reflect rural and urban populations, resulting in more accurate payments for ambulance services. Accordingly, we are adopting OMB's CBSA-based geographic area designations, which have been adopted for the IPPS, to more accurately identify urban and rural areas for ambulance fee schedule payment purposes. We are also adopting the most recent modification of the Goldsmith Modification, consistent with the provisions of section 1834(l), to more accurately determine rural census tracts within metropolitan areas.

These changes will affect whether certain areas are recognized as rural or urban. The distinction between urban and rural is important for ambulance payment purposes because ambulance payments are based on the point of pick-up for the transport, and the point of pick-up for urban and rural transport is paid differently. Of particular significance to the ambulance fee schedule, the changes would affect whether or not certain areas are eligible for certain rural bonus payments under the ambulance fee schedule. For example, the changes would affect whether or not certain areas are recognized as what we refer to as ''Super Rural Bonus'' areas established by section 414(c) of the MMA and set forth in section 1834(l)(12) of the Act. That section specifies that, for services furnished during the period July 1, 2004 through December 31, 2009, the payment amount for the ground ambulance base rate is increased by a ''percent increase'' (Super Rural Bonus) where the ambulance transport originates in a rural area (which includes Goldsmith areas) that we determine to be in the lowest 25th percentile of all rural populations arrayed by population density.

a. Core-Based Statistical Areas (CBSAs): Revised Office of Management and Budget (OMB) Metropolitan Area Definitions

In the February 27, 2002 final rule (67 FR 9100), we stated that we could not easily adopt and implement, within the timeframe necessary to implement the fee schedule, a methodology for recognizing geographic population density disparities other than MSA/nonMSA. We also stated that we would consider alternative methodologies that may more appropriately address payment to isolated, low-volume rural ambulance providers and suppliers at a later date. The application of any rural adjustment is determined by the geographic location of the beneficiary at the time he or she is placed on board the ambulance. We are now finalizing the adoption of OMB's revised geographic area designations for urban and rural areas and the most recent modification of the Goldsmith Modification to address payment to those isolated, low-volume rural providers and suppliers.

Prior to the 2000 decennial census, geographic areas were consistently defined by OMB as Metropolitan Statistical Areas (MSAs) with an MSA being defined as an urban area and

anything outside an MSA being defined as a rural area. In addition, for purposes of ambulance policy, we recognized the 1990 update of Goldsmith areas (generally, rural census tracts within counties that covered large tracts of land with one predominant urban area only) as rural areas (65 FR 55077 through 55100). In Fall 1998, OMB chartered the Metropolitan Area Standards Review Committee to examine the Metropolitan Area (MA) standards and develop recommendations for possible changes to those standards. Three notices related to the review of the standards were published on the following dates in the **Federal Register**, providing an opportunity for public comment on the recommendations of the Committee: December 21, 1998 (63 FR 70525 through 70561); October 20, 1999 (64 FR 56627 through 56644); and August 22, 2000 (65 FR 51059 through 51077).

In the December 27, 2000, **Federal Register** (65 FR 82227 through 82238), OMB announced its new standards. In that notice, OMB defined a CBSA, beginning in 2003, as ''a geographic entity associated with at least one core of 10,000 or more population, plus adjacent territory that has a high degree of social and economic integration with the core as measured by commuting ties.'' CBSAs are conceptually areas that contain a recognized population nucleus and adjacent communities that have a high degree of integration with that nucleus. The purpose of the new OMB standards is to provide nationally consistent definitions for collecting, tabulating, and publishing Federal statistics for a set of geographic areas.

The OMB standards designate and define two categories of CBSAs: Metropolitan Statistical Areas (MSAs); and Micropolitan Statistical Areas (65 FR 82227 through 82238). According to OMB, MSAs are based on urbanized areas of 50,000 or more population and Micropolitan Statistical Areas (referred to in this discussion as Micropolitan Areas) are based on urban clusters of at least 10,000 population but less than 50,000 population. Counties that do not fall within CBSAs are deemed ''Outside CBSAs.''

Under the ambulance fee schedule, MSAs would continue to be recognized as urban areas and all other areas outside MSAs (including Micropolitan Areas, areas ''Outside CBSAs'', and areas that are determined to be rural under the most recent modification of the Goldsmith Modification) would be recognized as rural areas. As noted previously, these designations are important because under the ambulance fee schedule, Medicare transports are designated either urban or rural based on the pick-up point of the transport.

As of June 6, 2003, the new OMB definitions recognized 49 new MSAs and 565 new Micropolitan Areas, and extensively revised the composition of many of the existing MSAs. There are 1,090 counties in MSAs under the new definitions (previously, there were 848 counties in MSAs). Of these 1,090 counties, 737 are in the same MSA as they were prior to the changes, 65 are in a different MSA, and 288 were not previously designated to any MSA (69 FR 49027).

There are 674 counties in Micropolitan Areas. Of these, 41 were previously in an MSA, while 633 were not previously designated to an MSA. There are five counties that previously were designated to an MSA, but are no longer designated to either an MSA or a new Micropolitan Area (Carter County, Kentucky; St. James Parish, Louisiana; Kane County, Utah; Culpepper County, Virginia; and King George County, Virginia) (69 FR 49027).

Our adoption of CBSA-based geographic area designations means that ambulance providers and suppliers that pick up Medicare beneficiaries in areas that are now outside of MSAs (but had been within MSA areas) may experience increases in payment, while those ambulance providers and suppliers that pick up Medicare beneficiaries in areas that are now within MSA areas (but had been outside of MSAs) may experience decreases in payment.

The use of updated geographical areas means the recognition of new urban and rural boundaries based on the population migration that occurred over a 10-year period, between 1990 and 2000.

We believe that updating the MSA definition to conform with OMB's CBSA-based geographic area designations, coupled with updating the Goldsmith Modification (that is, using the current Rural Urban Commuting Areas (RUCAs) version, as discussed in section III.B.1.b of this final rule), will more accurately reflect the contemporary urban and rural nature of areas across the country for ambulance payment purposes and cause ambulance fee schedule payments to become more accurate.

As of October 1, 2004, the IPPS adopted OMB's revised metropolitan area definitions to identify ''urban areas'' for payment purposes. Under the IPPS, MSAs are considered urban areas and Micropolitan Areas and areas ''Outside CBSAs'' are considered rural areas as specified in § 412.64(b). We are adopting similar CBSA-based designations of ''urban area'' and ''rural area'' under the ambulance fee schedule for the reasons discussed. Therefore, we are revising § 414.605 to include a definition of urban area and to reflect OMB's revised CBSA-based geographic area designations in our definition of rural area.

Comment: Some commenters suggested that we should mitigate any financial impact of the CBSA-based geographic changes by holding negatively-affected ambulance companies harmless or by adopting a phase-in of the CBSA-based geographic changes.

Response: While we understand the concern of some ambulance companies about the CBSA-based geographic changes, we think most negative impacts will be mitigated when we incorporate the updated Goldsmith Modification using RUCAs, as we discuss in section III.B.1.b. of this final rule. The RUCAs allow us to continue to recognize sub-county rural areas in CBSA-based MSAs. Further, we believe that accurate payments to rural areas should not be further delayed. Ambulance payments will not reflect the population changes documented by the CY 2000 decennial census and reflected in CBSA-based geographic designations until CY 2007. Finally, ambulance providers and suppliers who benefit from the floor amount based on Regional fee schedules will continue to receive transition payments through CY 2009, mitigating the overall financial impacts of the ambulance fee schedule.

Comment: Several commenters suggested delaying the implementation of the CBSA-based geographic changes until the findings of the GAO report on costs and access as they relate to ambulance services is published. The final report is currently due to be published by December 2007.

Response: We contacted the GAO concerning this report. At this time, the draft findings are not available and GAO is not permitted to discuss the report until its release. In view of the mitigating effects of our use of RUCAs, and in light of the fact that no ''super rural bonus'' areas are affected by the CBSA-based geographic designations, we think that the better course of action is to finalize our adoption of CBSA-based urban and rural designations. However, we will maintain contact with the GAO and, when their findings are available, we will consider whether any further adjustments are necessary.

b. Updated Goldsmith Modification: Rural Urban Commuting Areas (RUCAs)

The Goldsmith Modification evolved from an outreach grant program sponsored by the Office of Rural Health

Policy of the Health Resources and Services Administration (HRSA). This program was created to establish an operational definition of rural populations lacking easy access to health services in Large Area Metropolitan Counties (LAMCs). Dr. Harold F. Goldsmith and his associates created a methodology for identifying rural census tracts located within a large metropolitan county of at least 1,225 square miles. Using a combination of data on population density and commuting patterns, census tracts were identified as being so isolated by distance or physical features that they were more rural than urban in character. The original Goldsmith Modification was developed using data from the 1980 census. To more accurately reflect current demographic and geographic characteristics of the nation, HRSA's Office of Rural Health Policy, in partnership with the Department of Agriculture's Economic Research Service and the University of Washington, developed an update to the Goldsmith modification designated as Rural-Urban Commuting Area Codes (RUCAs) (69 FR 47518 through 47519).

Rather than being limited to LAMCs, RUCAs use urbanization, population density, and daily commuting data to categorize every census tract in the country. Thus, RUCAs are used to identify rural census tracts in all metropolitan counties. Section 1834(l) of the Act requires that we use the most recent modification of the Goldsmith Modification to determine rural census tracts within MSAs. Therefore, we are removing the definition of ''Goldsmith modification'' at § 414.605 and incorporating a reference to the most current version of the Goldsmith modification, which are the Rural Urban Commuting Areas (RUCAs), in the definition of ''rural area.''

Comment: We received numerous comments from members of the ambulance industry that were concerned about the geographic status of their pick-up areas. Ambulance companies located in areas that have been traditionally recognized as rural areas were concerned that population shifts based on whole county designations might not accurately reflect pockets of rurality within those counties.

Response: The most recent modification of the Goldsmith Modification, which we are adopting in this final rule, uses RUCAs to recognize levels of rurality in census tracts located in every county across the nation. As a result, many counties that are designated urban at the county level based on population do, indeed, have rural census tracts within them that will be recognized as rural areas through our use of RUCAs. While this may not mean that every commenter will be ultimately satisfied, we believe that using RUCAs to identify sub-county rural areas within urban counties will resolve many of the commenters' concerns.

Comment: Although a number of commenters were supportive of our use of RUCAs, they requested that we clarify how we intend to define rurality using RUCA categories.

Response: The RUCA system is an updated version of the Goldsmith Modification that uses a 10-point scale of rurality. RUCA levels are assigned to a census tract based on the association of a given area's population to the nearest urban commuting area as follows:

(1) Metropolitan-area core: Primary flow within an urbanized area (UA).

(2) Metropolitan-area high commuting: Primary flow 30% or more to a UA.

(3) Metropolitan-area low commuting: Primary flow 5 percent to 30 percent to a UA.

(4) Large town core: Primary flow within a place of 10,000 to 49,999.

(5) Large town high commuting: Primary flow 30 percent or more to a place of 10,000 to 49,999.

(6) Large town low commuting: Primary flow 5 percent to 30 percent to a place of 10,000 to 49,999.

(7) Small town core: Primary flow within a place of 2,500 to 9,999.

(8) Small town high commuting: Primary flow 30 percent or more to a place of 2,500 to 9,999.

(9) Small town low commuting: Primary flow 5 percent to 30 percent to a place of 2,500 to 9,999.

(10) Rural areas: Primary flow to a tract without a place of 2,500 or more.

Furthermore, census tracts under RUCAs can be broken down by zip code for every county, allowing us to modify rural and urban areas within a given county. In the May 26, 2006 proposed rule (71 FR 30358), we did not specify where we would draw the line on the RUCA scale for urban/rural purposes. According to HRSA, the generally accepted breakpoint is to define a level less than 4.0 on the scale as urban and levels equal to or greater than 4.0 on the scale as rural. Under section 330A of the Public Health Service Act, the Office of Rural Health Policy within HRSA determines eligibility for its rural grant programs through the use of the RUCA code methodology. Under this methodology, any rural census tract that is in a RUCA code 4.0 or higher is determined to be a rural census tract. We agree with the majority of the commenters who suggested that we follow HRSA's guidelines and consider areas to be rural if they fall within RUCA levels 4 through 10. One commenter suggested that a rurality level of 2.0 might be a better breakpoint for EMS purposes. However, we believe that HRSA's guidelines accurately identify rural areas for ambulance payment purposes and are generally consistent with Medicare payment policies. We will, therefore, consider any census tract falling at or above RUCA level 4.0 to be a rural area for purposes of payment for ambulance services. We are finalizing our proposal to use the most recent modification of the Goldsmith Modification incorporating RUCAs, as directed by section 1834(l) of the Act. We will use 4.0 on the RUCA scale as the delineation between rural and urban (4.0 and greater is rural and less than 4.0 is urban).

Comment: One commenter discussed zip code areas that ''bleed'' from one type of geographic area to another, such as from rural to urban. This commenter was concerned that zip codes that were predominantly, but not totally, located within a rural area would not receive rural payments for ambulance pick-ups in those areas due to the urban influence of part of the zip code area.

Response: When we review a claim for ambulance services, we specifically examine the zip code for the pick-up point to determine whether that zip code contains both urban and rural areas. Census tracts under RUCAs can be broken down by zip code for every county, which allows us to identify rural and urban areas within a given county. Generally, we would categorize a zip code as urban or rural, and make payment accordingly, based on where the bulk of the population in that zip code resides.

Comment: Several commenters were concerned about the impact of the proposed CBSA-based geographic changes on the provisions of the Medicare Modernization Act (MMA) for rural service areas, specifically concerning the ''Super Rural Bonus'' areas.

Response: The ''Super Rural Bonus'' areas are areas that we determine to be in the lowest 25th percentile of all rural populations arrayed by population density in accordance with section 1834(l)(12) of the Act. Ambulance pick-ups in these areas currently receive a 22.6 percent add-on to their Medicare payments. None of the Super Rural Bonus areas should be adversely affected by the proposed CBSA-based changes, as our use of RUCA levels will preserve the rural status of an area

whether or not it is located in a county which is designated as urban under the OMB definitions. Areas that do lose their rural status to become urban have become urban because of a significant increase in the surrounding population.

Comment: One commenter stated that the ambulance is dispatched to the patient to provide care at his or her pick-up point and, therefore, the ambulance payment system should reflect this procedure. Another commenter suggested that we should retain the Goldsmith Modification in its current form and not update payments under the ambulance fee schedule to reflect the use of RUCAs.

Response: We agree that the ambulance pick-up point is the determining factor in establishing payment under the ambulance fee schedule, and we intend to retain this procedure in the payment process. In addition, we agree that we need to recognize levels of rurality, and are doing so by adopting the updated Goldsmith Modification which uses RUCAs to identify rural areas within urban counties. We are directed by section 1834(l) of the Act to use the most recent update of the Goldsmith Modification in the payment process.

Comment: Another commenter suggested that we allow ambulance companies to present data to justify rurality, similar to the IPPS hospital reclassification process.

Response: Once again, we understand the concern of some ambulance companies to retain the rural status of their pick-up areas. However, as discussed in this section, we believe that, where applicable, the use of the RUCAs, and our ability to identify rural zip codes within census tracts, will address this concern in a consistent manner. Therefore, we do not believe it is necessary to complicate the payment process by developing an additional data submission and evaluation methodology. While the commenter directly referred to the hospital reclassification process that is administered under the IPPS, wherein hospitals can apply for geographic reclassification for purposes of determining the wage index adjustment to their inpatient payments, the hospital reclassification process was established by statute specifically for inpatient hospitals. Therefore, this IPPS reclassification methodology does not apply to ambulance services.

2. Specialty Care Transport (SCT)

In the February 27, 2002 **Federal Register** (67 FR 9100), we published a final rule with comment period entitled ''Fee Schedule for Payment of Ambulance Services and Revisions to the Physician Certification Requirements for Coverage of Nonemergency Ambulance Services'' that implemented the ambulance fee schedule. In that final rule, we defined SCT in § 414.605 as the ''interfacility transportation of a critically injured or ill beneficiary by a ground ambulance vehicle, including medically necessary supplies and services, at a level of service beyond the scope of the EMT [(Emergency Medical Technician)]—Paramedic. SCT is necessary when a beneficiary's condition requires ongoing care that must be furnished by one or more health professionals in an appropriate specialty area, for example, nursing, emergency medicine, respiratory care, cardiovascular care, or a paramedic with additional training.''

Additionally, ambulance vehicle staff must be certified as emergency medical technicians and legally authorized to operate all lifesaving and life-sustaining equipment that are on board the vehicle as specified in § 410.41(b)(1). Typically, a SCT level of care occurs when the patient, who is already receiving a high level of care in the transferring facility, requires a further level of care that the transferring facility is not able to provide.

We implemented the SCT level of payment for hospital-to-hospital ground ambulance transports upon implementation of the ambulance fee schedule on April 1, 2002 and we defined SCT at § 414.605. The definition of SCT in § 414.605 refers to ''interfacility transportation.'' As we stated in the preamble to the February 27, 2002 final rule with comment period (67 FR 9100), the SCT level of care includes the situation where a beneficiary is taken by ground ambulance from the hospital to an air ambulance and then from the air ambulance to the final destination hospital. Also, we stated in the preamble for both the September 12, 2000 proposed rule (65 FR 55077) and the February 27, 2002 final rule (67 FR 9108), that SCT was proposed as a level of interhospital service. As stated in our May 26, 2006 proposed rule, we based our payment for SCT-level ground ambulance transports on hospital-to-hospital ambulance transportation data.

Subsequent to the implementation of the ambulance fee schedule, we clarified our definition of SCT as hospital-to-hospital transport in a Program Memorandum to Medicare contractors, which was issued on September 27, 2002. (Program Memorandum Intermediaries/Carriers, Transmittal AB–02–130—Change Request 2295, September 27, 2002). That document and subsequent questions and answers related to the definition of SCT were made available to the public on the Ambulance policy Web page on the CMS Web site.

In addition, we clarified our definition of SCT in the Medicare Benefit Policy Manual, Chapter 10—Ambulance Services, in which we stated that SCT is regarded as a highly-skilled level of care of a critically injured or ill patient during transfer from one hospital to another. We have also clarified our policy in Ambulance Open Door Forums, conference calls, and oral and paper communication written in response to questions posed by individuals and groups representing the ambulance industry.

Despite our previous attempts to clarify the scope of SCT transport, we continued to receive questions from ambulance suppliers and providers and there was confusion on this point among the Medicare contractors. For this reason, we had proposed to change the definition of ''specialty care transport'' at § 414.605 to read ''hospital-to-hospital'' transport as opposed to ''interfacility'' transportation to conform our regulation text to our existing policy.

Comment: Many commenters suggested that we expand the SCT level of ambulance service to include transportation for neonates and adults transported from the scene of an accident to a hospital, as well as transport between hospitals and between hospitals and skilled nursing facilities (SNFs). In addition, commenters requested a clearer definition of the terms ''hospital'' and ''critical care.'' Some commenters suggested that we reconvene the Negotiated Rulemaking Committee to develop a definition of ''critical care.''

Response: We carefully considered the commenters'' recommendations to expand our interpretation of the term ''interfacility'' to include other origin and destination points in addition to hospitals. The SCT level of transport is intended to be used only for transfer of the most critically ill beneficiaries, who require ongoing specialized care beyond the scope of the EMT-paramedic. Typically, SCT level transport occurs when a beneficiary who is already receiving a high level of specialized care in one facility is moved to another facility to receive more specialized services. Although such specialized care is usually provided in a hospital, we recognize that some beneficiaries receive specialized care in a skilled nursing facility (SNF) and may require the SCT level of transport from the SNF to a hospital or from a hospital to a SNF.

Therefore, we are withdrawing our proposal to revise § 414.605 to read ''hospital-to-hospital'' instead of ''interfacility'' and expanding our interpretation of ''interfacility'' to include both hospitals and SNFs. In addition, in response to comments, we are further clarifying the kinds of facilities that we include as origin or destination points for ''interfacility'' transport for SCT purposes.

Many of our Medicare contractors indicate that they have been administering the ''interfacility'' requirement in the SCT definition broadly, paying claims at the SCT level of service beyond the scope of ''hospital-to-hospital.'' An examination of the latest available claims data shows that SCT-level payments are made predominantly for hospital-to-hospital transportation, as expected, with a small percentage of SCT-level ambulance transports involving other origin and destination points, primarily SNFs.

Therefore, for purposes of SCT payment, we consider a ''facility'' to include a SNF or a hospital that participates in the Medicare program. In addition, we consider the term ''facility'' to include a hospital-based facility that meets our requirements for provider-based status, as specified at § 413.65. Facilities that meet our requirements for provider-based status, like the main provider with which they are affiliated, are held to high standards of safety and patient care. Therefore, we believe that such facilities, due to their close association with a Medicare hospital and their adherence to high standards of care under our regulations, are also among the facilities equipped to provide the SCT level of care to patients and to provide the additional specialized care that is required under the SCT level of ambulance transport. We will continue to enforce our medical necessity requirements concerning all interfacility transports so that we can remain assured that they are occurring for only the most critical patients.

We appreciate the request by commenters that we clarify the kinds of facilities we consider to be included for SCT payment purposes. As explained above, our claims data indicate that SCT level care is needed primarily during inter-hospital transfers and, in some cases, during transfers between a hospital and a SNF. Therefore, for purposes of SCT payment, we consider a ''facility'' to include only a SNF or a hospital that participates in the Medicare program, or a hospital-based facility that meets our requirements for provider-based status.

Medicare hospitals include, but are not limited to, rehabilitation hospitals, cancer hospitals, children's hospitals, psychiatric hospitals, Critical Access Hopitals (CAHs), inpatient acute-care hospitals, and Sole Community Hospitals (SCHs).

However, we do not agree with commenters who recommended that a more comprehensive definition of ''critical care'' is warranted at this time. The Negotiated Rulemaking Committee was unable to precisely define ''critical care'' at the time it originally convened and recognized that a definition provided at the State or local level would be expected to fit, since there are no national standards available (Summary Minutes, Medicare Ambulance Fee Schedule Negotiated Rulemaking, October 4 and 5, 1999). We have no additional data that would permit us to develop a more precise definition at this time. In addition, we believe that a more precise definition might conflict with State or local parameters already in place, as well as possibly limiting the scope of SCT payments in localities where a broader State or local definition would otherwise apply.

''Critical care'' will continue to be interpreted by our Medicare contractors in conjunction with directives provided at the State or local level.

Comment: Many commenters also suggested that we consider including the ongoing monitoring of a patient by a specially-trained health care professional, beyond the scope of the EMT-Paramedic, to be within the realm of the SCT level of service.

Response: We carefully considered these commenters' concerns, and we agree that in cases where a critically injured or ill patient requires the SCT-level of transport from one facility to another, the ongoing care that must be furnished by a health professional in an appropriate specialty area, beyond the scope of the EMT-Paramedic, may include ongoing determinations as to whether the patient requires specialized care during the transport. We do not require that specialized treatment actually be furnished during the transport to satisfy the standard for SCT-level transport. However, we do require that the need for specialized treatment can only be ascertained by a health professional with specialized training beyond the scope of the EMT-Paramedic. We agree with commenters who indicated that an ambulance service should not be expected to bear the cost of an additional health professional to accompany a patient ''just in case'' the need for specialized treatment arises during transport. When such ''specialized monitoring'' is medically necessary, we agree that it is part of the ongoing care that falls within the definition of SCT.

Comment: One commenter stated that certain modifiers, such as the ''D'' modifier representing a stand-alone emergency room or the ''I'' modifier used when transferring a patient from the airport or helipad to the ambulance, exclude these types of ambulance transports from the SCT level of service.

Response: The commenter is correct that we generally do not recognize either ''D'' or ''I'' modifier-type ambulance transports to be SCT level ambulance services. The ''D'' modifier would be used to describe a non-hospital-based, non-hospital-owned, or non-hospital-operated diagnostic facility or clinic. We have defined the SCT level of ambulance service as interfacility ground transportation, involving transport between hospitals, hospital-based facilities and SNFs. Therefore, a stand-alone emergency room that is not provider-based or a freestanding clinic that is not provider-based would not meet the requirements for an origin or destination point for SCT level transport. The ''I'' modifier indicates an origin or destination that is a transfer point between ambulances, such as transfer from air to ground ambulance service at a helicopter pad. Unless the origin of the first leg of the transport is a facility and unless the SCT level of care is medically necessary after the transfer occurs, we would not consider the transport from the transfer point to the final destination to be SCT level transport.

3. Recalibration of the Ambulance Fee Schedule Conversion Factor

In the February 27, 2002 final rule with comment period (67 FR 9102 and 9103), we indicated that we would adjust the CF if actual experience under the fee schedule was significantly different from the assumptions used to determine the initial CF and air ambulance rates. We specifically stated that we would monitor payment data and evaluate whether the assumptions used were accurate.

We have continued to review our assumptions annually to determine whether or not a CF adjustment is warranted. We examined the effects of the relative volumes of the different levels of ambulance services (service mix) and the extent of low billing charges to determine whether we should adjust the CF to reflect actual practices. In the 4 years since the implementation of the ambulance fee schedule, no significant differences from our original assumptions have emerged. We have observed only insignificant differences, and, to date, no adjustments in any 1

year have been warranted. It is for this reason that we believe it is appropriate to discontinue our annual review of the original CF assumptions. We also believe that the formal annual review of air ambulance rates should be discontinued as we will monitor all ambulance rates and make adjustments on an ''as needed'' basis. The ambulance industry has available multiple venues for notifying us of potential issues. These include the ambulance fee schedule open door forums and telephone calls to designated CMS personnel. As an additional safeguard, we generally conduct a review of ambulance data each year in preparation for issuing the Ambulance Inflation Factor (AIF).

Therefore, we are revising § 414.610 (g) to indicate that we will monitor payment and billing data on an ongoing basis and adjust the CF and air ambulance rates as appropriate to reflect annual practices under the fee schedule.

Comment: Commenters were supportive of our proposal to discontinue the annual practice of examining the low biller data and the CF via the rulemaking process.

Response: We appreciate the support of the commenters on these points.

We are finalizing our proposal to discontinue the annual practice of examining the low biller data and the CF, as well as air ambulance rates, and to change the language at § 414.610(g) to reflect this.

4. Hospital-to-Hospital Ambulance Service: Emergency Response

In § 414.605, we define ''emergency response'' for purposes of ambulance service to mean ''responding immediately at the BLS (Basic Life Support) or ALS1 (Advanced Life Support Level 1) level of service to a 911 call or the equivalent in areas without a 911 call system. An immediate response is one in which the ambulance entity begins as quickly as possible to take the steps necessary to respond to the call.'' In our February 27, 2002 final rule with comment period (67 FR 9100), in our definition of ''emergency response'' we stated that the additional payment for emergency response is for the additional overhead cost of maintaining the resources required to respond immediately to a call and not for the cost of furnishing a certain level of service to the beneficiary.

The current emergency response definition has created confusion for those transports that originate at a hospital emergency department and the ambulance is transporting the beneficiary to an emergency department at another hospital for either admittance or treatment. For example, in most of these cases, the beneficiary must be stabilized prior to the transport. Therefore, the need to maintain a state of readiness to respond immediately to an urgent call, warranting a higher emergency response payment, does not appear to be applicable to these situations.

Another example occurs when the ambulance is owned by the originating hospital. We stated in a Program Memorandum to the Medicare contractors (Transmittal AB–02–130, Change Request 2295, September 27, 2002) that upon receipt of a call for ambulance services, the dispatcher makes the determination of whether the call constitutes an Emergency response. When the ambulance service is already readily available at the originating hospital, an emergency call may not be necessary, much less through a dispatcher for a 911 service.

While we recognize that there may be instances when an emergency response payment is warranted for a transport between two hospital emergency departments, we believe that payment based on readiness to respond immediately is not justified 100 percent of the time. For this reason, we believed our current definition of Emergency response needed to be clarified to reflect only circumstances where payment for immediate response is truly warranted. We proposed to revise the definition of Emergency response to mean that an ambulance entity—

- Maintains readiness to respond to urgent calls at the BLS or ALS1 level of service; and
- Responds immediately at the BLS or ALS1 level of service to 911 calls, the equivalent in areas without a 911 call system or radio calls within a hospital system when the ambulance entity is owned and operated by the hospital.

Comment: We received many comments on revising the definition of ''emergency response''. Most commenters expressed concern that this revised definition would put private ambulance services at a disadvantage. They interpreted our proposed definition to include only ambulance services owned and operated by hospitals that respond to radio calls within a hospital system. Essentially, their interpretation of our proposed definition was that only ambulance services owned and operated by hospitals would be able to transport patients at the ''emergency response'' level of service and, therefore, be able to receive the higher ''emergency response'' payment as a result.

Response: Certainly, this was not our intent. Our view of the problem we were attempting to address was the issue of ''readiness'' when responding to a 911 call. We expect ''emergency response'' payment to be made only in circumstances where readiness to respond immediately is truly required. Therefore, we proposed to clarify the circumstances under which we expected this to occur. However, we agree with comments stating that ambulance service calls generally do not originate through a 911 service but through the hospital's radio dispatch at the location where the ambulance is stationed. Private ambulance services stationed at inpatient hospitals would, therefore, be at a disadvantage if we specify that responding to hospital radio calls only qualifies as ''emergency response'' when the ambulance entity is owned or operated by the hospital. This would not affect off-site ambulance services whose calls originate through a 911 or equivalent service. We agree that the proposed change in the definition of ''emergency response'' could have an unintended adverse effect on private ambulance services in these circumstances.

Comment: Several commenters stated that our existing definition of emergency response more clearly reflects the intent of the Negotiated Rulemaking Committee in that all ambulance services should have equal access to the use of the emergency level of service by accessing it through established State protocols, such as 911 or an equivalent service.

Response: We also agree that the current definition of emergency response is consistent with the Negotiated Rulemaking Committee's intent and does not present other problems raised by commenters. For the BLS and ALS1 levels of service, an ambulance service that qualifies for an emergency response is assigned a higher relative value to recognize the additional costs incurred in responding immediately. We think that requiring an ambulance service to respond to a 911 call, or the equivalent in areas without a 911 call system, satisfies this requirement.

Therefore, we are withdrawing our proposal to revise the ''emergency response'' definition and will retain the current definition at 414.605. We expect that the State protocol (a 911 call or the equivalent in areas without a 911 call system) for requesting emergency ambulance services will be followed in all instances.

C. Analysis of and Responses to Public Comments

We received a total of 102 timely public comments in response to the May 26, 2006 proposed rule (71 FR 30358). Commenters included national trade associations, health care providers, hospitals, CMS contractors, and private citizens.

All public comments were reviewed and grouped by like or related topics. Comments are addressed in the individual sections of discussion to which they apply.

D. Ambulance Inflation Factor (AIF) for 2007

Section 1834(l)(3)(B) of the Act provides the basis for updating payment amounts for ambulance services. Our regulations at § 414.610(f) provide that the ambulance fee schedule must be updated by the AIF annually, based on the CPI for all urban consumers (CPI-U) (U.S. city average) for the 12-month period ending with June of the previous year. For CY 2007, that percentage is 4.3 percent.

Section 414.620 specifies that changes in payment rates resulting from incorporation of the AIF will be announced by notice in the **Federal Register** without opportunity for prior comment. We find it unnecessary to undertake notice and comment rulemaking because the statute and regulations specify the methods of computation of annual updates. This notice does not change policy, but merely applies the update methods specified in the statute and regulations.

The national fee schedule for ambulance services has been phased in over a 5-year transition period beginning April 1, 2002 as specified in § 414.615.

Prior to January 1, 2006, during the transition period, the AIF was applied separately to both the fee schedule portion of the blended payment amount (regardless of whether a national or regional fee schedule applied) and to the reasonable cost or charge portion of the blended payment amount, respectively, for each ambulance provider or supplier. Then, these two amounts were added together to determine the total payment amount for each provider or supplier. Beginning January 1, 2006, the total payment for air ambulance providers and suppliers is based on 100 percent of the national ambulance fee schedule, while the total payment amount for ground ambulance providers and suppliers is based on either 100 percent of the national ambulance fee schedule or a combination of the national ambulance fee schedule and the regional ambulance fee schedule. As of January 1, 2007, the combination rate will be 80 percent of the national ambulance fee schedule and 20 percent of the regional ambulance fee schedule.

IV. Five-Year Refinement of Relative Value Units Under the Physician Fee Schedule: Responses to Public Comments on the Five Year Review of Work Relative Value Units

A. Scope of the Five-Year Review

This final rule includes the culmination of the third 5-Year Review of work RVUs required by the statute. The work RVUs affected by this review will be effective for services furnished beginning January 1, 2007.

In the June 29, 2006 proposed notice, ''Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology'', we explained the process used to conduct the 5-Year Review of work RVUs. In response to our solicitation of public comments that appeared in the November 15, 2004 **Federal Register** (69 FR 66370), we received comments from approximately 35 specialty groups, organizations, and individuals involving over 500 Current Procedural Terminology (CPT) codes. After review by our medical staff, we shared these comments with the AMA's Relative Value Update Committee (RUC) along with additional services we had identified as potentially misvalued.

After a comprehensive review process, the RUC submitted work RVU recommendations for all of these codes except for the codes that were withdrawn or referred to the CPT Editorial Panel for further review or action, and CPT code 32020 for which no specialty society expressed an interest in conducting a survey. We analyzed all of the RUC recommendations by evaluating the methodology used by each workgroup to develop the recommendations, the recommended work RVUs, and the rationale for the RUC recommendations. When appropriate and feasible, if we had concerns about the application of a particular methodology, we assessed whether the recommended work RVUs were appropriate by using alternative methodologies.

In conducting our review of the RUC recommendations we considered whether: (1) The code was part of a completed survey process; (2) the methodology used by the specialty society followed the standard RUC process; (3) the survey respondents stated the work had or had not changed in the past 5 years; (4) databases (for example, Society of Thoracic Surgeons (STS), National Surgical Quality Improvement Program (NSQIP), and Medicare diagnosis-related group (DRG)) were used in lieu of the standard RUC methodology or as a supplement to the standard methodology; and (5) the intra-service work per unit of time (IWPUT) calculation was used to determine work RVUs in lieu of the standard RUC process. Although we recognize that the work values of codes may change over time, it is the responsibility of the specialty society to present compelling evidence that a code is misvalued. (For additional information on the review process, please see the June 29, 2006 proposed notice (71 FR 37172).)

B. Review of Comments

Many commenters expressed support for our proposed valuations of many of the services. However, other commenters expressed specific concern or disagreement with the proposed valuation of approximately 106 codes, with the major concern being that the codes would be undervalued.

We convened a multi-specialty panel of physicians to assist us in the review of comments. The comments we did not submit for panel review are discussed at the end of this section. The panels were moderated by our medical staff and consisted of:

- Clinicians representing the commenting specialty(s), based on our determination of those specialties which are most identified with the services in question. Although commenting specialties were welcomed to observe the entire refinement process, they were only involved in the discussion of those services for which they were invited to participate.
- Primary care clinicians nominated by the American Academy of Family Physicians (AAFP) and the American College of Physicians.
- Four carrier medical directors.
- One to two clinicians who practice in related specialties and have knowledge of the services under review.

We submitted 30 codes for evaluation by the panel. The panel discussed the work involved in each procedure under review in comparison to the work associated with other services on the fee schedule. We assembled a set of reference services and asked the panel members to compare the clinical aspects of the work for services they believed were incorrectly valued to one or more of the reference services. In compiling the reference set, we attempted to include: (1) Services that are commonly furnished for which work RVUs are not

(i) The decision regarding the specific chemotherapeutic agents to test is made at least 14 days after discharge;

(ii) The specimen was collected while the patient was undergoing a hospital surgical procedure;

(iii) It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;

(iv) The results of the test do not guide treatment provided during the hospital stay; and,

(v) The test was reasonable and medically necessary for the treatment of an illness.

(4) For purposes of this section, ''chemotherapy sensitivity test'' means a test identified by the Secretary as a test that requires a fresh tissue sample to test the sensitivity of tumor cells to various chemotherapeutic agents. The Secretary identifies such tests through program instructions.

Subpart H—Fee Schedule for Ambulance Services

■ 18. Section 414.605 is amended by—

■ A. Removing the definition of ''Goldsmith modification.''

■ B. Revising the definition of ''rural area.''

■ C. Adding the definition of ''urban area'' in alphabetical order.

The revisions and addition read as follows:

§ 414.605 Definitions.

* * * * *

Rural area means an area located outside an urban area, or a rural census tract within a Metropolitan Statistical Area as determined under the most recent version of the Goldsmith modification as determined by the Office of Rural Health Policy of the Health Resources and Services Administration.

* * * * *

Urban area means a Metropolitan Statistical Area, as defined by the Executive Office of Management and Budget.

■ 19. Section 414.610 is amended by revising paragraph (g) to read as follows:

§ 414.610 Basis of payment.

* * * * *

(g) *Adjustments.* The Secretary monitors payment and billing data on an ongoing basis and adjusts the CF and air ambulance rates as appropriate to reflect actual practices under the fee schedule. These rates are not adjusted solely because of changes in the total number of ambulance transports.

Subpart J—Submission of Manufacturer's Average Sales Price Data

■ 20. Section 414.802 is amended by adding the definition of ''Bona fide service fees'' in alphabetical order to read as follows:

§ 414.802 Definitions.

* * * * *

Bona fide service fees means fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

* * * * *

■ 21. Section 414.804 is amended by revising paragraphs (a)(1) through (a)(4) to read as follows:

§ 414.804 Basis of payment.

(a) * * *

(1) The manufacturer's average sales price for a quarter for a drug represented by a particular 11-digit National Drug Code must be calculated as the manufacturer's sales to all purchasers in the United States for that particular 11-digit National Drug Code (after excluding sales as specified in paragraph (a)(4) of this section and then deducting price concessions as specified in paragraphs (a)(2) and (a)(3) of this section) divided by the total number of units sold by the manufacturer in that quarter (after excluding units associated with sales as specified in paragraph (a)(4) of this section).

(2) *Price concessions.* (i) In calculating the manufacturer's average sales price, a manufacturer must deduct price concessions. Price concessions include the following types of transactions and items:

(A) Volume discounts.

(B) Prompt pay discounts.

(C) Cash discounts.

(D) Free goods that are contingent on any purchase requirement.

(E) Chargebacks and rebates (other than rebates under the Medicaid program).

(ii) For the purposes of paragraph (a)(2)(i), bona fide services fees are not considered price concessions.

(3) To the extent that data on price concessions, as described in paragraph (a)(2) of this section, are available on a lagged basis, the manufacturer must estimate this amount in accordance with the methodology described in this paragraph.

(i)(A) For each National Drug Code with at least 12 months of sales (including products for which the manufacturer has redesignated the National Drug Code for the specific product and package size and has 12 months of sales across the prior and current National Drug Codes), after adjusting for exempted sales, the manufacturer calculates a percentage equal to the sum of the price concessions for the most recent 12-month period available associated with sales subject to the average sales price reporting requirement divided by the total in dollars for the sales subject to the average sales price reporting requirement for the same 12-month period.

(B) For each National Drug Code with less than 12 months of sales, the calculation described in paragraph (i)(A) of this section is performed for the time period equaling the total number of months of sales.

(ii) The manufacturer multiplies the applicable percentage described in paragraph (a)(3)(i)(A) or (a)(3)(i)(B) of this section by the total in dollars for the sales subject to the average sales price reporting requirement (after adjusting for exempted sales) for the quarter being submitted. (The manufacturer must carry a sufficient number of decimal places in the calculation of the price concessions percentage in order to round accurately the net total sales amount for the quarter to the nearest whole dollar.) The result of this multiplication is then subtracted from the total in dollars for the sales subject to the average sales price reporting requirement (after adjusting for exempted sales) for the quarter being submitted.

(iii) The manufacturer uses the result of the calculation described in paragraph (a)(3)(ii) of this section as the numerator and the number of units sold in the quarter (after adjusting for exempted sales) as the denominator to calculate the manufacturer's average sales price for the National Drug Code for the quarter being submitted.

(iv) *Example.* After adjusting for exempted sales, the total lagged price concessions (discounts, rebates, etc.) over the most recent 12-month period available associated with sales for National Drug Code 12345–6789–01 subject to the ASP reporting requirement equal $200,000, and the total in dollars for the sales subject to the average sales price reporting requirement for the same period equals $600,000. The lagged price concessions percentage for this period equals 200,000/600,000 = 0.33333. The total in dollars for the sales subject to the