

Report to Congressional Committees

June 2007

MEDICARE ULTRASOUND PROCEDURES

Consideration of Payment Reforms and Technician Qualification Requirements





Highlights of GAO-07-734, a report to congressional committees

Why GAO Did This Study

Medicare spending on imaging services, among which are ultrasound procedures that use sound waves to facilitate diagnosis, nearly doubled from 1999 to 2004. The Congress required GAO to examine Medicare's payment methods for ultrasound procedures and whether the technicians that conduct them-called sonographers—should be subject to qualification standards, such as having to undergo a certification process called credentialing. This report addresses (1) the ultrasound procedures commonly used to diagnose medical conditions of Medicare beneficiaries, particularly for beneficiaries in a skilled nursing facility (SNF), (2) the financial impact of changing how Medicare pays for ultrasound exams and associated equipment and ambulance transportation for beneficiaries in a SNF, and (3) the factors for the Centers for Medicare & Medicaid Services (CMS) to consider in determining whether to establish credentialing or other requirements for sonographers. For this review, GAO analyzed Medicare claims data and conducted interviews and literature reviews.

What GAO Recommends

CMS should require sonographers providing Medicare-covered ultrasound exams to either be credentialed or work in an accredited facility. CMS stated that it would consider this recommendation.

www.gao.gov/cgi-bin/getrpt?GAO-07-734.

To view the full product, including the scope and methodology, click on the link above. For more information, contact A. Bruce Steinwald at (202) 512-7114 or steinwalda@gao.gov.

MEDICARE ULTRASOUND PROCEDURES

Consideration of Payment Reforms and Technician Qualification Requirements

What GAO Found

Three-fourths of the approximately 41 million ultrasound procedures provided to Medicare beneficiaries in 2005 in any setting were one of two types: (1) echocardiograms to diagnose heart conditions or (2) noninvasive vascular procedures used to monitor blood flow and detect blockage or injury in veins and arteries. Ultrasound procedures consist of the ultrasound exam itself and the physician's interpretation of the exam. Nearly all of the ultrasound exams provided under Medicare Part B, which covers physician, hospital outpatient, diagnostic testing, and certain other services, were performed in physicians' offices and hospital outpatient departments. Of these exams, less than 1 percent were conducted in SNFs or homes, generally using ultrasound equipment that was transported to these settings by a mobile provider. Among beneficiaries in SNF stays not covered by Medicare who received ultrasound exams in SNFs, noninvasive vascular exams were the most prevalent type performed.

Two ultrasound procedure payment changes affecting SNF beneficiaries that GAO examined would likely increase expenditures and beneficiary cost sharing. If CMS had paid to transport ultrasound equipment to beneficiaries in SNF stays not covered by Medicare, which is not currently done, Medicare expenditures could have increased by an estimated \$9.8 million and beneficiary cost sharing could have been about \$2.6 million higher in 2005, assuming the number and location of services would not change in response to this policy. Moreover, paying separately for ultrasound exams and related transportation during beneficiaries' Medicare-covered SNF stays, as opposed to bundling these and other services into a single daily payment as CMS currently does, could have increased Medicare payments by about \$22.0 million and beneficiary cost sharing by about \$13.4 million in 2005, assuming no change in service use due to the revised policy. The actual financial impact for Medicare could differ from these estimates if, for example, providers increased their service provision due to these policy changes.

Factors for CMS to consider in determining whether to establish credentialing or other qualification requirements for sonographers include the evidence of the value of setting such requirements and variation in federal requirements for sonographers. The skill of the sonographer conducting an ultrasound is critical for its use to support a physician's correct diagnosis; poorly captured images can lead to misdiagnoses or unnecessarily repeated exams. Findings from several peer-reviewed studies, the Medicare Payment Advisory Commission, and ultrasound-related professional organizations support requiring that sonographers either have credentials or operate in facilities that are accredited, where specific quality standards apply. In some localities and practice settings, CMS or its contractors have required that sonographers either be credentialed or work in an accredited facility. Medicare's inconsistent requirements undermine assurance that beneficiaries are receiving high-quality services across the country.

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Abbreviations

AIUM An	nerican Institute of Ultrasound in Medicine	
AIUM AII	ierican institute of Offrasound in Medicine	

ARDMS American Registry for Diagnostic Medical Sonography

BBA Balanced Budget Act of 1997
BETOS Berenson-Eggers Type of Service

CCI Cardiovascular Credentialing International
CMS Centers for Medicare & Medicaid Services
CoP Medicare Conditions of Participation
CPT Current Procedural Terminology
FDA Food and Drug Administration

HCPCS Healthcare Common Procedure Coding System
HHS Department of Health and Human Services

ICAVL Intersocietal Commission for the Accreditation of Vascular

Laboratories

IDTF independent diagnostic testing facility

LCD Local Coverage Determination

MedPAC Medicare Payment Advisory Commission

NCD National Coverage Determination

NCH National Claims History
OIG Office of Inspector General
PPS prospective payment system
SAF Standard Analytical File
SNF skilled nursing facility

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United States Government Accountability Office Washington, DC 20548

June 28, 2007

The Honorable Max Baucus Chairman The Honorable Charles Grassley Ranking Minority Member Committee on Finance United States Senate

The Honorable John D. Dingell Chairman The Honorable Joe Barton Ranking Minority Member Committee on Energy and Commerce House of Representatives

The Honorable Charles B. Rangel Chairman The Honorable Jim McCrery Ranking Minority Member Committee on Ways and Means House of Representatives

Medicare spending on imaging services nearly doubled from \$5.7 billion in 1999 to \$10.9 billion in 2004, in part due to growth in the number of procedures. Diagnostic ultrasound procedures, an imaging service which uses high-frequency sound waves to create images of internal body organs and blood flow, accounted for about one-fourth of this spending in 2004. Growth in the use of diagnostic ultrasound procedures has been due in part to technological advances, which have improved the quality of ultrasound images and physicians' ability to employ them to diagnose

¹See Medicare Payment Advisory Commission (MedPAC), *A Data Book: Healthcare Spending and the Medicare Program*, June 2006. MedPAC is an independent federal body established by law to advise the Congress on issues affecting the Medicare program, including its payment methods. MedPAC's data cited here are based on Medicare Part B payments under the physician fee schedule and include beneficiary cost sharing. Medicare Part B covers physician services, hospital outpatient services, diagnostic tests, and ambulance services as well as certain other services such as physical therapy.

²See MedPAC 2006.

medical conditions. Technological advances also have led to the development of ultrasound devices that are smaller and more portable. The enhanced portability of ultrasound equipment has made it easier for beneficiaries to receive ultrasound exams in skilled nursing facilities (SNF) or beneficiaries' homes to which ultrasound equipment generally must be transported by a mobile provider.

Ultrasound procedures consist of two parts—the ultrasound exam itself and the physician's interpretation of the exam. The first part of the procedure—the ultrasound exam—generally involves an ultrasound technician called a sonographer taking the image. The second part of the procedure is the physician's interpretation of images from the ultrasound exam. Medicare, administered by the Centers for Medicare & Medicaid Services (CMS), pays for the ultrasound exam and the physician's interpretation of it separately or together.

Medicare covers ultrasound and other imaging procedures and certain related transportation under Part A and Part B of the program, and beneficiaries are responsible for part of the cost of these services through cost sharing.⁵ For all beneficiaries, Medicare covers the physician's interpretation of ultrasound exams under Part B. For beneficiaries in a Part A-covered SNF or hospital inpatient stay, Medicare covers most services under Part A and pays for them through a prospective payment system (PPS), which involves bundling payment for multiple services. Specifically, for beneficiaries in Part A-covered SNF stays, payment for ultrasound exams and medically necessary ambulance transportation is bundled with other services into a single daily rate. A PPS gives providers the incentive to furnish services efficiently because if the actual cost of services is less than the bundled payment, the provider keeps the difference. For beneficiaries who are not in a Part A-covered SNF or hospital inpatient stay, which includes those in a noncovered SNF stay, Medicare covers ultrasound exams and medically necessary ambulance transportation under Part B.

³CMS refers to ultrasound exams as "technical components" and physicians' interpretations of images from these exams as "professional components."

⁴CMS is an agency within the Department of Health and Human Services (HHS), to which HHS has delegated responsibility for administering the Medicare program.

 $^{^5\}mathrm{Medicare}$ Part A covers in patient hospital, skilled nursing facility, hospice care, and some home health care.

The rapid growth in spending for imaging has contributed to interest in the Congress and the Medicare Payment Advisory Commission (MedPAC) about whether Medicare's payment methodology for these services creates the proper incentives for appropriate use. Further, MedPAC has expressed concern that not all imaging providers have the ability to conduct quality exams, and several ultrasound-related professional organizations have raised this issue with regard to sonographers. Becoming credentialed by a nationally recognized organization, which can require obtaining a combination of training and experience and passing an examination, is one way for sonographers to demonstrate that they have the necessary skill level to perform quality exams. In addition, accreditation is a mechanism for facilities that conduct ultrasound procedures to demonstrate that their affiliated sonographers meet the standards necessary to perform quality exams. For example, to work in an accredited facility, sonographers may be required to have certain credentials or be working toward obtaining them.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 required that we assess issues associated with providing ultrasound procedures to Medicare beneficiaries. As discussed with the committees of jurisdiction, we address the following issues in this report: (1) the types of ultrasound procedures commonly used to diagnose medical conditions of Medicare beneficiaries, particularly those in SNFs, (2) the financial impact of changing how Medicare pays for ultrasound exams and associated equipment and ambulance transportation for beneficiaries receiving care in a SNF, and (3) the factors to consider in determining whether CMS should establish credentialing or other qualification requirements for sonographers.

To examine the types of diagnostic ultrasound procedures provided to Medicare beneficiaries and the sites of service where the exams were performed, we analyzed Medicare claims data for 2005. Our analysis of the types of procedures provided to all Medicare beneficiaries was based on claims for physicians' interpretations of ultrasound exams, which are paid under Part B regardless of whether the exam itself was covered under

⁶The American Registry for Diagnostic Medical Sonography (ARDMS) is one example of a nationally recognized organization that credentials sonographers.

⁷See Pub. L. No. 108-173, § 513, 117 Stat. 2066, 2300.

⁸The claims data that we used came from the National Claims History (NCH) carrier file, and the Standard Analytical File (SAF) outpatient claims files.

Part A or Part B. Our analysis of the site of service of ultrasound procedures was based on claims for ultrasound exams that were paid under Part B because Part A payments for these exams are bundled with other services and not separately reported in the Medicare claims data. To understand clinical issues associated with the site of service, we performed a literature search; conducted structured interviews with representatives of gerontological, radiological, and other ultrasoundrelated professional organizations; and reviewed CMS documents. To estimate the financial impact to Medicare and its beneficiaries of providing payments for ultrasound equipment transportation and of paying separately for ultrasound exams and associated equipment and ambulance transportation for beneficiaries in Part A-covered SNF stays, we analyzed Medicare claims data for ultrasound exams and ambulance services in 2005 and for exams in 1995 through 1997. We found the Medicare claims data we analyzed to be sufficiently reliable for the purposes of this report. 11 To identify factors to consider in determining whether CMS should establish credentialing or other requirements for sonographers, we reviewed Medicare regulations, CMS documents, Medicare carriers' credentialing requirements for sonographers, and relevant literature and also interviewed officials from agencies and organizations such as CMS, MedPAC, and those that credential sonographers. ¹² Appendix I provides more detail on our scope and methodology. We performed our work from July 2006 through May 2007 in accordance with generally accepted government auditing standards.

⁹The organizations interviewed included the American Geriatrics Society, the American Medical Directors Association, the American College of Radiology, the American Society of Echocardiography, the Society for Vascular Surgery, and the Society for Vascular Ultrasound; four mobile ultrasound providers that provide services to SNFs and nursing homes in various states; and representatives from the National Association for the Support of Long-Term Care and the American Association of Homes and Services for the Aging.

 $^{^{10}}$ Medicare only covers ambulance transportation that is medically necessary. See CMS, $Medicare\ Benefit\ Policy\ Manual$, Chapter 10, §10.2, 10.2.1, May 28, 2004.

¹¹The Medicare claims data are used by the Medicare program as a record of payments to health care providers and are monitored by CMS.

¹²The credentialing organizations included the American Registry for Diagnostic Medical Sonography (ARDMS), the Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL), and the American Institute of Ultrasound in Medicine (AIUM).

Results in Brief

The most common diagnostic ultrasound procedures provided to all Medicare beneficiaries and to those in noncovered SNF stays were used to diagnose heart and circulatory (vascular) problems. Echocardiograms, used to diagnose conditions such as heart failure and problems with the innermost layer of the heart, were the most frequently performed type of ultrasound procedure in 2005. They accounted for about 53 percent of the 41 million procedures provided to nearly 12.4 million Medicare beneficiaries in any setting and 49 percent of the \$3.2 billion in Medicare Part B payments for ultrasound procedures. Noninvasive vascular studies—used to examine the blood flow through veins and arteries and to detect blockage, injury, or blood clots—represented about 20 percent of the ultrasound procedures and 30 percent of the Medicare Part B payments. Nearly all (99 percent) of the ultrasound exams provided to beneficiaries under Medicare Part B in 2005 were performed in physician offices and hospital outpatient departments. The remaining 1 percent were conducted in various sites of service, including about 129,000 exams conducted in SNFs and 101,000 exams conducted in beneficiaries' homes. Among the ultrasound exams provided in SNFs to beneficiaries in noncovered SNF stays, noninvasive vascular studies were the most prevalent, followed by echocardiograms.

We examined two potential changes to Medicare payment methods related to ultrasound procedures for beneficiaries in SNFs and found that both are likely to increase Medicare expenditures and beneficiary cost sharing based on 2005 data and assuming that the provision of exams would not change in response to this policy. First, we found that providing Part B payments to transport equipment to SNFs during noncovered SNF stays for ultrasound exams could have increased Medicare expenditures by about \$9.8 million and beneficiary cost sharing by about \$2.6 million in 2005. Second, we estimated the impact of paying separately under Part B for ultrasound exams and associated equipment and ambulance transportation for beneficiaries in Part A-covered SNF stays, as opposed to bundling these services into the Part A PPS payment as is currently done. We found that this policy could have increased Part B Medicare expenditures by about \$22.0 million and beneficiary cost sharing by about \$13.4 million in 2005. However, these types of changes in payment policies could affect service use and thus could cause the actual financial impact to differ from our estimates. For example, paying separately under Part B for ultrasound exams and associated equipment and ambulance transportation for beneficiaries in Part A-covered SNF stays could cause the use of these services to grow because the PPS incentive to provide them efficiently would be absent, and this could cause the actual financial impacts to be greater than our estimates. In addition, unless these separate Part B payments were offset by a reduction in the Part A PPS payment, they would increase overall Medicare expenditures.

Factors for CMS to consider in determining whether to establish credentialing or other requirements for sonographers include the evidence of the value of establishing such requirements and the variation in federal requirements for sonographers. Having qualified sonographers is important because their skill in performing an ultrasound exam is critical to capturing quality images that physicians can use in making appropriate clinical decisions and avoiding misdiagnoses or unnecessarily repeated exams. Findings from peer-reviewed studies, MedPAC, and ultrasoundrelated professional organizations support the establishment of qualification requirements for sonographers. In some locations and practice settings, Medicare mandates that certain sonographers either be credentialed or work in an accredited facility that requires sonographers to demonstrate that they meet certain quality standards. The inconsistency of Medicare's requirements across the country, coupled with the absence of state licensure requirements for sonographers, undermines the assurance that beneficiaries are receiving similarly high-quality services in different locations and settings.

To help ensure consistency in the quality of ultrasound services provided to Medicare beneficiaries nationwide, we recommend that the Administrator of CMS require that sonographers serving Medicare beneficiaries either be credentialed or work in an accredited facility.

In its written comments on a draft of this report, CMS stated that it would consider our recommendation but would prefer that states engage their own licensing bodies in implementing sonographer licensure programs. (See app. VI.) CMS stated that a national policy would not take into account regional variation in factors such as access to care and state licensing requirements. We agree that access is an important issue when considering whether to implement a national policy, and our report states that a regulation could include a phase-in period to provide noncredentialed sonographers with time to comply with the newly imposed requirements. Furthermore, although CMS asserted that states should engage their own licensure bodies to implement sonographer licensure programs, we reported that state licensing requirements for sonographers do not exist. Consequently, we continue to believe that CMS should implement our recommendation and develop a national policy establishing sonographer qualification requirements.

Background

Ultrasound is a noninvasive form of imaging that, unlike X-ray and certain other diagnostic modalities, does not expose patients to the risks associated with the emission of ionizing radiation. To perform a diagnostic ultrasound exam, a sonographer applies a hand-held medical device called a transducer to the skin through which the ultrasound machine emits and receives sound waves. As the sonographer moves the transducer around the patient's body, an image of the various organs or blood flow under study appears on a monitor. The sonographer electronically stores what he or she considers as the most diagnostically useful images.

The ultrasound systems that sonographers use differ along multiple dimensions, including their types of transducers, documentation capabilities, and cost. The type and number of transducers on a given ultrasound system depend on the parts of the body to be examined and the conditions intended to be diagnosed. In addition, some ultrasound systems have additional documentation capability, which allows sonographers and other health care personnel to electronically transmit and display ultrasound images. According to the ultrasound device manufacturers with whom we spoke, an ultrasound machine can range in price from \$20,000 to \$200,000 or more. Prices are partially based on the system's features, such as the number and type of different transducers it has and its capacity to store and transmit data.

Sonographer Credentialing and Training and Facility Accreditation

Sonographers can demonstrate that they have the appropriate level of training and experience by becoming credentialed by a nationally recognized organization. The American Registry for Diagnostic Medical Sonography (ARDMS) and Cardiovascular Credentialing International (CCI) are two main sonographer credentialing organizations. Each organization has multiple pathways to becoming credentialed that are designed to account for differences in sonographers' training and experience. CCI allows sonographers without formal education, but with experience in the field, to take its credentialing exam, but ARDMS requires that all sonographers have a combination of education and experience to take its exam.

Sonographers can obtain formal training through numerous education programs. For example, the Commission on Accreditation of Allied Health Education Programs lists 151 programs for diagnostic medical sonographers, including associate's degree programs from community colleges as well as bachelor's degree programs. Individuals we spoke with from ultrasound-related professional organizations noted that, although

sonographers are more likely than in the past to undergo formal training, there are still practicing sonographers who do not have it.

Several organizations offer accreditation for facilities that conduct ultrasound procedures as a way to demonstrate that they meet the standards necessary to perform quality exams. 13 To work in an accredited facility, sonographers may be required to have certain credentials or have received a minimum number of training hours. For example, sonographers working in facilities that are accredited by the Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL) must either be credentialed or have a specified level of training and experience in sonography. Similarly, for a facility to become accredited by the American Institute of Ultrasound in Medicine (AIUM), the sonographers who work there must either be credentialed by ARDMS or become credentialed before re-accreditation, which occurs every 3 years. 14 This allows new sonographers to obtain experience conducting exams, which they need to be eligible to take a credentialing exam, such as from ARDMS and CCI. In addition to requirements for sonographers, accreditation can address broader aspects of ultrasound procedures, including qualification requirements for physicians, the condition of the ultrasound equipment, patient safety, images produced, and documentation.

Medicare and Its Coverage Processes

Medicare is the federally financed health insurance program for persons age 65 and older and certain individuals with disabilities. The program serves over 42 million beneficiaries. Eligible individuals are automatically covered by Part A, which helps pay for inpatient hospital, skilled nursing facility, and hospice care, as well as some home health care. Most eligible individuals elect to pay a monthly premium to obtain Medicare Part B coverage, which covers physician services, hospital outpatient services, and certain other services, such as physical therapy. In addition to the

¹³These organizations include the American College of Radiology, the American Institute of Ultrasound in Medicine, the Intersocietal Commission for the Accreditation of Vascular Laboratories, and the Intersocietal Commission for the Accreditation of Echocardiography Laboratories.

¹⁴Certification by the American Registry of Radiologic Technologists is also acceptable if the facility is applying for accreditation in breast ultrasound.

¹⁵Medicare also covers individuals with end-stage renal disease.

premium, beneficiaries are required to pay an annual Part B deductible as well as coinsurance of 20 percent for most Part B services.¹⁶

Medicare covers items or services that are provided for by statute and that meet the applicable criteria for coverage when furnished to a particular beneficiary. Decisions on the extent to which, and under what circumstances, Medicare will cover specific services, procedures, or technologies may be made by CMS or its contractors in a number of ways. At the national level, CMS can make National Coverage Determinations (NCD) that apply across the country. More typically, most coverage issues are decided on the local level through Local Coverage Determinations (LCD) or other decisions made by the contractors that pay Medicare claims. For Part B claims for physician services, the contractors that pay claims and create LCDs are generally called carriers. If fan NCD or other authority does not provide specific guidance about the conditions for covering a service, procedure, or technology, the carrier has the discretion to adopt an LCD to address the issue. LCDs only apply to a carrier's service area or to the providers it serves.

Medicare Payment for Ultrasound Procedures and Associated Ambulance and Equipment Transportation Medicare covers physicians' interpretations of ultrasound and other imaging exams under Part B for all beneficiaries. For beneficiaries, except for those in a Part A-covered hospital or SNF stay, Medicare also provides Part B coverage of ultrasound and other imaging exams as well as medically necessary ambulance transportation. How Medicare pays for ultrasound exams and associated ambulance transportation for beneficiaries in a SNF depends on whether Medicare covers the stay under Part A. For beneficiaries in Part A-covered SNF stays, Medicare bundles

¹⁶Beneficiaries' coinsurance can be higher than 20 percent for Part B-covered services provided in a hospital outpatient facility.

¹⁷CMS has begun a process of using competition to choose its Medicare claims processing contractors and is awarding new contracts to entities called Medicare Administrative Contractors. When this process is complete, these contractors will review and pay all Part B claims.

¹⁸Medicare covers skilled nursing and rehabilitative therapy for beneficiaries being treated in SNFs for conditions related to a hospital stay lasting at least 3 days and occurring within 30 days before admission to the SNF. For beneficiaries who qualify, Medicare pays under Part A for most necessary services, including room and board, nursing care, and ancillary services such as drugs, laboratory tests, and physical therapy, for up to 100 days per benefit period. A benefit period begins when a Medicare beneficiary is admitted to a hospital or a SNF and ends when he or she has not been an inpatient of these facilities for 60 consecutive days. Beneficiaries are responsible for a daily copayment after the 20th day of SNF care, regardless of the cost of services received.

payment for one part of the ultrasound procedure—the exam—as well as associated ambulance transportation into the daily Part A PPS payment. ¹⁹ When beneficiaries remain in a SNF after exhausting their Part A SNF benefits or if the SNF stay is not covered for some other reason, they are in a "noncovered" SNF stay during which Medicare covers ultrasound exams and medically necessary ambulance transportation under Part B.

Although nearly all Medicare services provided to beneficiaries in Part A-covered SNF stays are paid through the Part A PPS payment, certain services are paid for separately under Part B.²⁰ The Balanced Budget Act of 1997 (BBA) excluded from the Part A PPS payment all physician services for beneficiaries in Part A-covered SNF stays, which include interpretations of ultrasound and other imaging exams, and provides for separate payments for these services under Part B.²¹ In addition, certain categories of services—for example, the exam for computed tomography (CT) scans, magnetic resonance imaging (MRI), and angiography—are excluded from the Part A PPS payment and are paid for separately under Part B when provided in a hospital outpatient setting. CMS identified these services as ones that "lie well beyond the scope of care that SNFs would ordinarily furnish."²² (See table 1.) One of our previous reports noted that CMS considered the possibility of paying separately for certain ultrasound

¹⁹Under the SNF PPS, the SNF receives a single daily payment for almost all Part A- and Part B-covered services provided to a SNF resident. Certain items and services are excluded from the PPS by statute and thus are paid for separately under Part B. In conjunction with the PPS, each SNF is responsible for billing Medicare for almost all services provided during a Part A-covered SNF stay, including services rendered by an outside supplier.

²⁰For a discussion of the services paid for separately for beneficiaries in Part A-covered SNF stays, see GAO, *Skilled Nursing Facilities: Services Excluded from Medicare's Daily Rate Need to be Reevaluated*, GAO-01-816 (Washington, D.C.: Aug. 22, 2001).

²¹See Pub. L. No. 105-33, § 4432, 111 Stat. 251, 414-22.

²²See Health Care Financing Administration Program Memorandum A-00-01 (January 2000).

exams and associated ambulance transportation but decided not to do so because they did not meet the criteria used to identify such services.²³

Table 1: Medicare Payment Methodology for Selected Imaging Procedures and Associated Transportation for Beneficiaries in SNF Stays

	Part A-covered SNF stays			Noncovered SNF stays		
Type of procedure or transportation	Ultrasound	X-ray ^a	CT scan, MRI, Angiography⁵	Ultrasound	X-ray ^a	CT scan, MRI, Angiography ^b
Imaging procedures						
Exam	•	•	O°	0	0	0
Interpretation of exam	0	0	0	0	0	0
Ambulance transportation associated with imaging exam ^d	•	•	O°	0	0	0

Source: GAO analysis of CMS guidance on Medicare payment methodology for SNF services.

Legend: • = bundled into SNF PPS payment; ○ = paid separately under Part B

^aDoes not include angiography.

^bAngiography is a type of imaging procedure that involves the use of X-rays to develop images of arteries after dye is injected into the bloodstream.

Exams and associated ambulance transportation are only paid for separately under Part B if the exam is conducted in a hospital outpatient facility.

^dMedically necessary ambulance transportation is paid for separately from the PPS payment under Part B when associated with dialysis and with the following services if provided in a hospital outpatient department: cardiac catheterization, MRI, CT scan, certain ambulatory surgery procedures, emergency services, radiation therapy, angiography, and lymphatic and venous procedures. See CMS, *Skilled Nursing Facility Consolidated Billing as it Relates to Ambulance Services*, MLN Matters No. SE0433 (2005).

Medicare does not make separate Part B payments to transport ultrasound equipment to a home or SNF for an exam. The transportation of the ultrasound equipment and sonographer is considered to be bundled into the ultrasound exam payment. However, Medicare does make separate

²³See GAO-01-816. CMS used three criteria to identify services to be paid for separately under Part B during Part A-covered SNF stays—these services were required to be (1) high cost, (2) infrequently needed by SNF beneficiaries, and (3) unlikely to be overprovided. CMS decided that doppler flow studies, a type of ultrasound procedure, did not meet the first or second of these criteria and thus should not be paid for separately under Part B. Similarly, CMS decided that ambulance transportation not already paid for separately under Part B—for example, ambulance service to transport a beneficiary from a SNF to another location for an ultrasound exam—should not be paid for separately because this service did not meet the first of these criteria.

Part B payments for the transportation and set-up of equipment used to conduct diagnostic X-ray exams.²⁴

Policy concerning payment for the transportation of ultrasound equipment has changed over time. Prior to 1996, CMS did not have a national policy concerning the transportation of ultrasound equipment, but some of its carriers developed their own policies to cover it. In 1995, carriers for 14 states and the northern part of California had a policy to reimburse providers for additional transportation costs associated with providing mobile ultrasound exams, as they did for mobile X-ray exams, which is another type of imaging service. However, beginning January 1, 1996, CMS determined that the statutory provision that provided coverage for the transportation of portable X-ray equipment did not provide this coverage for diagnostic ultrasounds and, therefore, carriers could no longer make separate Part B payments for the transportation of ultrasound equipment. Beginning 1996.

²⁴Section 1861(s)(3) of the Social Security Act provides coverage of diagnostic x-rays furnished in a Medicare beneficiary's place of residence. CMS determined that because of the increased costs associated with transporting x-ray equipment to the beneficiary, Congress intended to provide an additional payment amount for the transportation of equipment for services furnished by an approved portable x-ray supplier. See 60 *Fed Reg*. 63124, 63149 (1995). Thus, CMS established specific procedure codes to pay for the transportation of portable x-ray equipment.

 $^{^{25}}$ In California, while the carrier for the northern part of the state paid for ultrasound equipment transportation, the carrier for the southern part of the state did not.

²⁶CMS had also allowed carriers to develop their own policies concerning separate Part B payments for the transportation of electrocardiogram equipment. However, beginning January 1, 1997, carriers were no longer able to do so. Section 4559 of the BBA temporarily restored separate payments for the transportation of equipment for EKG tests performed during 1998 but not thereafter. This section did not address payments for the transportation of ultrasound equipment. See Pub. L. No. 105-33, § 4559, 111 Stat. 251, 464.

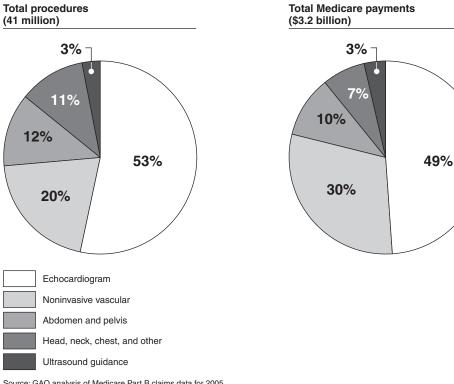
The Most Common Medicare Ultrasound Procedures in 2005 Were Echocardiograms and Noninvasive Vascular Studies Echocardiograms and noninvasive vascular procedures accounted for about three-fourths of the approximately 41 million ultrasound procedures provided to Medicare beneficiaries in 2005 in any setting. ²⁷ Nearly all of the ultrasound exams paid under Part B were performed in physician offices and hospital outpatient departments. The remaining 1 percent were conducted in various sites of service, including SNFs and beneficiaries' homes. Among the exams provided in SNFs to beneficiaries in noncovered SNF stays, noninvasive vascular studies were the most prevalent, followed by echocardiograms.

About Three-Quarters of Ultrasound Procedures Provided to All Beneficiaries in 2005 Were Echocardiograms and Noninvasive Vascular Studies

Echocardiograms, used to diagnose heart conditions, and noninvasive vascular studies, often used to diagnose blood clots, were the most common diagnostic ultrasound procedures provided to Medicare beneficiaries in 2005. (See fig. 1.)

²⁷The total number of procedures (41 million) is based on analysis of Medicare claims data for physician interpretations of ultrasound exams. These data account for procedures provided to all Medicare beneficiaries regardless of setting and whether the exams were paid under Part A or Part B.

Figure 1: Percentages of Total Procedures and Total Part B Medicare Payments for Ultrasound Procedures Provided to Beneficiaries, 2005



Source: GAO analysis of Medicare Part B claims data for 2005.

Notes: Percentages may not sum to 100 due to rounding. The number of procedures is based on claims for physicians' interpretations of ultrasound exams and claims for ultrasound procedures classified solely as physician services that did not have a separately billed exam and physician's interpretation of the exam. Medicare payments do not include beneficiary cost-sharing amounts. Our calculation of Medicare payments does not include payment for ultrasound exams that were provided to beneficiaries in Part A-covered SNF or inpatient hospital stays because Part A payments for these exams are bundled with other services and not separately reported in Medicare claims data.

Specifically, of the 41 million total procedures provided to nearly 12.4 million beneficiaries in 2005 in any site of service, the following apply.

Echocardiograms were the most frequently performed type of ultrasound, accounting for about 53 percent of the total number of procedures and 49 percent of Medicare Part B payments. Echocardiograms are commonly used to diagnose medical conditions such as heart failure, problems with the innermost layer of the heart or the respiratory system, and disorders of the heart rate.

- Noninvasive vascular studies represented about 20 percent of ultrasound procedures provided to beneficiaries and 30 percent of Medicare Part B payments for ultrasounds. Among other conditions, noninvasive vascular ultrasounds are used to monitor the blood flow through veins and arteries and to detect blockage, or blood clots. They are frequently used to diagnose deep vein thrombosis (DVT).²⁸
- Ultrasounds of the abdomen and pelvis accounted for about 12 percent of the ultrasound procedures and 10 percent of Medicare Part B payments for ultrasounds. Abdominal ultrasounds are commonly used to identify disorders of the kidney and ureter, tumors, and disorders of the urinary tract.
- Ultrasounds of the head, neck, chest, and other ultrasound procedures, accounted for about 11 percent of the total number of Medicare ultrasound procedures and 7 percent of Part B Medicare payments. Cataracts and disorders of the breast were among the top medical conditions diagnosed with these procedures.
- Ultrasound guidance procedures accounted for the remaining share—about 3 percent of the number of procedures and Part B Medicare payments. Ultrasound guidance is used, for example, to direct the placement of a needle to withdraw fluid from the membrane surrounding the heart or lungs or to guide the performance of breast, liver, and prostate biopsies. Some of these ultrasound procedures require the attendance of a physician in the room during the performance of the procedure. (In appendix II, see table 4 for details on the level of physician supervision required for different types of procedures and table 5 for the top five medical conditions diagnosed by type of procedure.)

Our analysis of the available site-of-service data showed that nearly all (99 percent) of the 28 million ultrasound exams provided to beneficiaries under Part B in 2005 were performed in physician offices and hospital

²⁸Deep vein thrombosis is a condition where a blood clot forms in a vein, usually in the lower leg. This condition can cause pain and swelling. If a clot breaks free and moves through the vascular system to the heart and lungs it can be fatal.

outpatient departments—68 percent and 31 percent, respectively. ²⁹ The remaining 1 percent (about 387,000 exams) were conducted in various sites of service, including SNFs and beneficiaries' homes. Of the 28 million ultrasound exams provided to Medicare beneficiaries under Part B, about 129,000 were conducted in SNFs for beneficiaries in noncovered SNF stays and about 101,000 were conducted in beneficiaries' homes.

Noninvasive Vascular Studies Were the Most Prevalent Ultrasound Exams Provided in SNFs to Beneficiaries in Noncovered SNF Stays

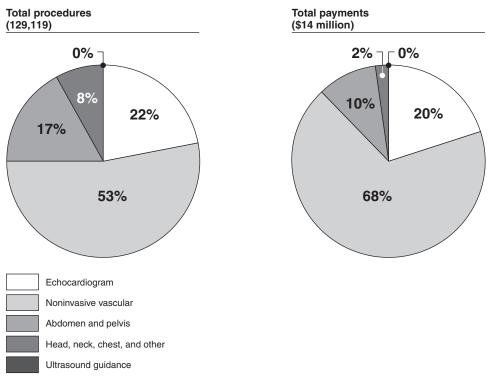
Of the 129,000 ultrasound exams conducted in SNFs for beneficiaries in noncovered SNF stays, noninvasive vascular procedures were the most common, accounting for 53 percent of the exams and 68 percent of the Medicare Part B payments.³⁰ The noninvasive vascular procedures were used to diagnose conditions such as disorders of the soft tissues, skin conditions, and deep vein thrombosis. Echocardiograms were the second most frequently performed ultrasound exam in SNFs for beneficiaries in noncovered SNF stays, representing 22 percent of the procedures and 20 percent of Part B Medicare payments. Ultrasounds of the abdomen or pelvis were also common among this population, accounting for about 17 percent of the ultrasound procedures and 10 percent of Medicare Part B payments. The remaining 8 percent of the procedures and 2 percent of Part B Medicare payments were for various other categories, including head, neck, and chest. Only 5 ultrasound guidance procedures were conducted in SNFs for this population in 2005. (See fig. 2 and table 6 in app. II, which shows the top 5 medical conditions diagnosed by type of procedure provided to beneficiaries in noncovered SNF stays.) Data limitations did not allow us to examine the site of service for approximately 262,000 ultrasound procedures provided to beneficiaries in Part A-covered SNF stays, but our analysis of the types of procedures

²⁹This number of exams is smaller than the total number of procedures discussed above (41 million total procedures) because it is based on the number of technical components (exams) associated with the image production, whereas the 41 million procedures are based on counts of the physician interpretations of the exam and the procedures classified solely as physician services. The 28 million exams excludes exams provided to beneficiaries in Part A-covered SNF or hospital inpatient stays that are bundled with other services under Medicare Part A and not reported separately in the Part B data.

³⁰These were exams that cost about \$14 million and were paid for separately under part B for beneficiaries whose SNF stay was not covered by Part A. Our site-of-service analysis of exams performed in SNFs focuses on beneficiaries that were not in Part A SNF stays because the data did not allow us to identify site of service for beneficiaries in Part A SNF stays. As noted earlier, payment for procedures provided in SNFs for Part A beneficiaries are not reported separately in the Part B data.

these beneficiaries received shows similar results to those provided in SNFs during noncovered stays.³¹

Figure 2: Percentages of Total Procedures and Total Part B Medicare Payments for Ultrasound Procedures Conducted in SNFs for Beneficiaries in Noncovered SNF Stays, 2005



Source: GAO analysis of Medicare Part B claims data for 2005.

Notes: We based this analysis on claims for ultrasound exams and claims for ultrasound procedures classified solely as physician services that do not include a separately billed exam and physician's interpretation of the exam. Medicare payments in this figure do not include beneficiary cost-sharing amounts. Our calculation of Medicare payments does not include those for ultrasound exams that were provided to beneficiaries in Part A-covered SNF or inpatient hospital stays because Part A payments for these exams are bundled with other services and not separately reported in Medicare claims data.

³¹For example, vascular procedures were the most prevalent (44 percent of the procedures) for this population, followed by echocardiograms (33 percent). Ultrasounds of the abdomen and pelvis accounted for 12 percent of the ultrasound procedures provided to those in Part A SNF stays. The remaining 11 percent of the procedures were for various other categories, including ultrasound guidance.

Because of congressional interest in the quality of ultrasound services, and particularly those conducted in SNFs, we examined clinical considerations associated with the site where exams were performed. Our literature search produced no pertinent studies on clinical issues associated with transporting elderly patients to obtain ultrasound exams as opposed to providing mobile services in SNFs or beneficiaries' homes. Our analysis of CMS's 2005 data on the level of physician supervision required to perform ultrasound procedures indicates that about 90 percent of them did not require a physician to be present. Thus, having a sonographer provide these procedures could be appropriate for mobile services provided in a SNF or home even if a physician was not present.

Representatives from nationally recognized professional organizations, including professionals in the fields of geriatrics and sonography, as well as ultrasound providers and long-term care provider organizations, provided their views on clinical considerations associated with transporting elderly patients to obtain an ultrasound or providing an ultrasound in a SNF. 32 In general, they said that the risks and benefits depend on the patient's condition—such as whether the beneficiary requires emergency care, the most appropriate setting for follow-up care, and the type of ultrasound services provided. For example, there are risks in transporting elderly patients, particularly those with certain medical conditions including dementia, who can become disoriented in new surroundings.³³ Some geriatricians, medical directors of SNFs, and longterm care providers said that moving patients could increase their risk of falls or fractures. A gerontologist and a geriatrician further noted that pain is a major issue to consider in caring for frail, bedridden patients. Transporting patients with deep vein thrombosis and pressure sores may expose them to skin tears and pain. On the other hand, certain ultrasound exams may be best performed in hospitals or physician offices, according to organization representatives that we contacted. For example, some

³²We conducted interviews with geriatricians and a gerontologist from the American Geriatrics Society and structured interviews with SNF medical directors who are members of the American Medical Directors Association. We also interviewed professionals from ultrasound-related organizations (the Society for Vascular Surgery, the Society for Vascular Ultrasound, and Society of Diagnostic Medical Sonography); four mobile ultrasound companies that provide services to the elderly in SNFs or nursing homes; and representatives of the National Association for the Support of Long-Term Care and the American Association of Homes and Services for the Aging.

³³In addition, patients may miss medication doses or meals, which can be serious for people with certain diseases, such as diabetes.

beneficiaries may require emergency care, and therefore require hospitalization. Others who need ultrasound exams may have conditions that involve risks of serious complications that could require surgical or other interventions more readily provided in a hospital. In addition, a hospital or physician's office may be the best setting for certain types of procedures, such as ultrasound guidance for needle placement during biopsies, which requires the presence of a physician during the performance of the procedure.

Changing Ultrasound
Payment Methods
Would Likely Increase
Expenditures and
Beneficiary Cost
Sharing

We addressed two potential changes to Medicare payment methods related to ultrasound procedures, both of which are likely to increase Medicare expenditures and beneficiary cost sharing.³⁴ The first potential change we addressed, which would involve paying to transport equipment to SNFs during noncovered SNF stays for ultrasound exams, could have increased Medicare expenditures by an estimated \$9.8 million and beneficiary cost sharing by an estimated \$2.6 million in 2005, assuming that this policy change would not affect the number and location of exams provided. The second potential change in Medicare payment methods involves paying separately under Part B for ultrasound exams and associated equipment and ambulance transportation during Part Acovered SNF stays, as opposed to bundling payments for these services as is done now. We found that paying separately under Part B for these services could have increased Part B Medicare payments by an estimated \$22.0 million and beneficiary cost sharing by an estimated \$13.4 million in 2005, assuming no change in the number of services provided as a result of this policy. However, because these revised payment policies could affect the use of these services, the actual financial impacts could differ from our estimates. For instance, paying separately under Part B for ultrasound exams and associated equipment and ambulance transportation during Part A-covered SNF stays could cause the use of these services to grow because the PPS incentive to provide services efficiently would be absent, so the actual impact of this policy could exceed our estimates. Further, unless these separate Part B payments were offset by a reduction in the Part A PPS payment, they would increase overall Medicare expenditures.

³⁴The financial impact estimates in this section are based primarily on Medicare claims data for 2005. Since 2005, there have been changes that could affect the use of ultrasound exams and associated equipment and ambulance transportation and thus also affect our estimates. These changes include those related to Medicare payment methodology as well as other changes, such as technological advances, that could affect service use. However, accounting for changes that occurred since 2005 and those that could occur in the near future is beyond the scope of this report.

Part B Equipment Transportation Payments Would Likely Increase Expenditures and Beneficiary Cost Sharing

Paying to transport ultrasound equipment for the 129,000 exams done in SNFs during noncovered SNF stays in 2005 could have increased Medicare expenditures by an estimated \$9.8 million and beneficiary cost sharing by an estimated \$2.6 million, assuming the number and location of exams would not have changed in response to this policy. If this policy also applied to mobile exams conducted in other sites of service, the financial impact could be greater. For example, if Medicare made separate Part B payments to transport ultrasound equipment to beneficiaries' homes, as is the case for the transportation of portable X-ray equipment, the financial impact could be higher by about \$4.4 million for Medicare expenditures and \$1.2 million higher for beneficiary cost sharing. Similarly, paying to transport ultrasound equipment to custodial care and assisted living facilities could have increased the financial impact of this policy further (see table 2).

Table 2: Financial Impact of Part B Ultrasound Equipment Transportation Payments, 2005

	Financial impact				
Site of service	Ultrasound exams (number)	Medicare payments (dollars)	Beneficiary cost sharing (dollars)		
Skilled nursing facilities ^a	129,119	\$9.8 million	\$2.6 million		
Home	101,285	\$4.4 million	\$1.2 million		
Custodial care and assisted living facilities	22,787	\$1.3 million	\$0.3 million		
Total	253,191	\$15.5 million	\$4.1 million		

Source: GAO analysis of Medicare Part B claims data for 2005.

Notes: Dollar amounts may not sum to totals due to rounding. To calculate the number of ultrasound exams, we counted the exams themselves that were paid under Part B, as well as ultrasound procedures classified solely as physician services that do not include a separately billed exam. Ultrasound exams were defined as Healthcare Common Procedure Coding System codes in the Berenson-Eggers Type of Service categories for echography in addition to 10 diagnostic ultrasound codes that were not in these categories. Calculations are based on the assumption that mobile ultrasound providers would receive a fee for transporting and setting up the equipment. See appendix I for more information on how we defined ultrasound exams and appendix III for detailed results.

^aBased on exams conducted in either a SNF or nursing facility during a noncovered SNF stay.

The actual financial impact of paying to transport ultrasound equipment to SNFs would differ from our estimates if this policy caused the number of mobile exams provided to increase or decrease, but this would not affect our determination that this policy would likely lead to higher Medicare expenditures and beneficiary cost sharing. The mobile providers we spoke with noted that Medicare payments to transport ultrasound equipment

would allow them to expand their service area and thus could increase the number of exams they provide. For example, one provider noted that transportation payments might allow it to serve beneficiaries in rural areas where doing so would have proved cost prohibitive before. Thus, payments to transport ultrasound equipment could potentially increase the number of mobile exams and provide more beneficiaries with access to these services.

Increasing access to mobile ultrasound exams could possibly lessen the need for ambulance services to transport beneficiaries from a SNF to another location for an ultrasound exam, which could in turn reduce the financial impact of this policy. Mobile providers stressed that Medicare and its beneficiaries save money when beneficiaries in SNF stays receive mobile exams in a SNF as opposed to being transported to another location, in part because payments and beneficiary cost sharing to transport ultrasound equipment are less than for an ambulance round trip. We identified about 13,900 exams that potentially could have been conducted in a SNF during a noncovered SNF stay rather than using ambulance transportation to travel to another location for the exam.³⁵ If the increased availability of mobile exams allowed all of these 13,900 exams to be conducted in a SNF rather than in the locations (such as a hospital outpatient facility) where they actually took place, the financial impact of this policy would have been about \$3.0 million lower for Medicare expenditures and about \$1.2 million lower for beneficiary cost sharing.36

However, if mobile providers increased the number of ultrasound exams conducted in SNFs and other locations, it is also possible that this increase could lead to larger than estimated increases in Medicare expenditures and beneficiary cost sharing. Some of the exams conducted for beneficiaries in noncovered SNF stays likely were conducted in other sites of service (for example, physicians' offices or hospital outpatient departments) but did not involve Medicare-covered ambulance services to

³⁵See appendix I for how we identified these exams.

³⁶These estimates take into account that (1) ultrasound equipment transportation (if it were covered) likely would, on average, be less expensive than ambulance transportation for Medicare and its beneficiaries—the average amount paid by Medicare and its beneficiaries for ultrasound equipment transportation (including the equipment set-up fee) for each of these 13,900 exams in 2005 was \$138, compared to \$514 for an ambulance round trip—and (2) Medicare expenditures and beneficiary cost sharing for an ultrasound exam can be different in a SNF compared to other locations such as a hospital outpatient facility.

transport the beneficiary there. If mobile providers furnished more ultrasound exams in SNFs by expanding their service area, some of these beneficiaries might have received exams in this site of service rather than in other locations. As a result of this change in the site of service for these exams, our estimated impacts on Medicare expenditures and beneficiary cost sharing could (1) increase because Medicare would be paying for the additional ultrasound equipment transportation cost that would otherwise not have been necessary and (2) change due to the different cost of the exams themselves in the new locations. However, data constraints do not allow us to estimate the extent to which this would occur.³⁷

Based on what mobile providers told us, one might expect the number of mobile exams to increase in response to the provision of payments to transport ultrasound equipment. However, our analysis of the effect of ceasing to pay for ultrasound equipment transportation in 1996 indicates that the opposite might occur. In 1995, Medicare carriers in 14 states and Northern California paid to transport ultrasound equipment, but these payments ceased in all localities as of January of 1996. We compared the growth rate in the number of exams conducted in SNFs in the 14 states where Medicare paid to transport ultrasound equipment in 1995 and stopped doing so thereafter to the rate across all other states where this change did not occur.³⁸ The number of exams conducted in SNFs grew by about 237 percent from 1995 to 1997 in states where Medicare paid to transport ultrasound equipment in 1995 and ceased doing so thereafter, which was substantially greater than the 62 percent growth rate in other states where Medicare had not paid to transport ultrasound equipment. This suggests that the elimination of Medicare payments to transport ultrasound equipment may have led to an increase in the number of mobile exams as the amount paid per exam decreased.³⁹

³⁷We were only able to identify exams conducted during noncovered SNF stays if they were conducted in a SNF or nursing facility because we did not have accurate data on which beneficiaries were in noncovered SNF stays. Therefore, we could not estimate the financial impact of a change in the site of service for exams conducted during noncovered SNF stays that were not conducted in a SNF or nursing facility.

³⁸See appendix III, table 8, for detailed results of this analysis. We excluded California from this analysis because the two Medicare carriers in this state did not have the same policy regarding payments to transport ultrasound equipment.

³⁹An increase in the number of exams conducted in SNFs following the elimination of transportation payments does not necessarily imply that the opposite would occur if these payments were reinstated.

These results raise the possibility that mobile providers might maintain or decrease the number of exams they provide if Medicare began paying to transport ultrasound equipment. A decrease in the number of exams conducted in SNFs, if it occurred, could require that more beneficiaries use ambulance services to be transported to other locations for the exams. We estimated that a reduction in the number of exams conducted in SNFs could cause the estimated increases in Medicare expenditures and beneficiary cost sharing to be greater.

Paying Separately for Ultrasound Services during Part A-Covered SNF Stays Would Likely Increase Part B Expenditures, Beneficiary Cost Sharing, and Service Use Paying separately under Part B for ultrasound exams and associated equipment and ambulance transportation during Part A-covered SNF stays, as opposed to bundling these services into the Part A PPS payment as is done now, could have increased Medicare Part B payments in 2005 by an estimated \$22.0 million and caused beneficiary cost sharing to rise by about \$13.4 million, assuming that this policy would not affect service use. (See table 3 and app. I for details on how these estimates were calculated.)

⁴⁰We have reported that about 40 percent of beneficiaries who received an ultrasound exam in a nursing home would require ambulance services to be transported to another site of service for the exam if mobile ultrasound services were unavailable. See GAO, *Medicare: Impact of Changing Transportation Policy for Portable Equipment is Uncertain*, GAO/HEHS-98-82 (Washington, D.C.: May 18, 1998).

⁴¹These estimates include up to \$2.6 million in Medicare payments and \$1.5 million in beneficiary cost sharing for up to 33,000 ultrasound exams for which Medicare appears to have improperly paid for separately under Part B. HHS's Office of Inspector General (OIG) is currently reviewing improper billing of services under Part B provided to beneficiaries in Part A-covered SNF stays that should have been covered under the PPS payment. OIG officials noted that Medicare contractors likely recouped these improper payments. However, if these contractors failed to recoup all of these improper payments, then we would have overestimated the financial impact of paying separately under Part B for these exams because Medicare would have already been paying separately under Part B for some of them in the absence of this policy. Because data for improperly paid claims do not indicate whether the payment was recouped, we are unable to accurately estimate the extent to which these improper payments affect our impact estimates. See appendix I for more detail.

Table 3: Increase in Part B Expenditures and Beneficiary Cost Sharing Due to Separate Payments for Ultrasound Services during Part A-Covered SNF Stays, 2005

Type of service	Increase in Part B expenditures (dollars)	Increase in beneficiary cost sharing (dollars)
Ultrasound exams ^a	\$19.5 million	\$12.7 million
Ultrasound equipment transportation ^b	\$2.3 million	\$0.6 million
Ambulance transportation for ultrasound exam°	\$0.2 million	\$0.1 million
Total	\$22.0 million	\$13.4 million

Source: GAO analysis of Medicare claims for 2005 and 1997 (see app. I for more detail).

Notes: Dollar amounts may not sum to totals due to rounding. Ultrasound exams were defined as Healthcare Common Procedure Coding System codes in the Berenson-Eggers Type of Service categories for echography in addition to 10 diagnostic ultrasound codes that were not in these categories. See appendix I for more detail.

^aEstimates based on physicians' interpretations of ultrasound exams conducted during Part A-covered SNF stays and estimates of the Medicare payment and beneficiary cost sharing for the exam that corresponds to these interpretations. See appendix I for more detail.

^bEstimates based on the assumption that Medicare would pay for both the transportation and set-up of the ultrasound equipment. If Medicare only paid for the transportation of ultrasound equipment, Part B expenditures due to separate Part B payments during Part A-covered SNF stays for this service would increase by about \$2.0 million, and beneficiary cost sharing would increase by approximately \$0.5 million.

°Defined as ambulance services used to transport a beneficiary from a SNF to another facility and back for an ultrasound exam.

The actual financial impact of paying separately under Part B for ultrasound exams and associated equipment and ambulance transportation could differ from the estimates in table 3 because this policy could cause their use to grow by undermining the incentive inherent in the PPS to efficiently provide these services. Although we did not find published studies specific to ultrasound or certain other imaging modalities predicting that this would occur, one of our previous reports found that bundling SNF services into a single PPS payment caused the use of therapy services to decrease. This suggests that paying separately under Part B for these services could possibly have the opposite effect and cause use to grow, which could also cause the actual financial impact of this policy to exceed our estimates. Similarly, MedPAC has reported that

⁴²GAO, Skilled Nursing Facilities: Providers Have Responded to Medicare Payment System By Changing Practices, GAO-02-841 (Washington, D.C.: Aug. 23, 2002).

there are efficiency gains from bundling payments.⁴³ In addition, both we and MedPAC have previously noted that bundling Medicare payments for certain end-stage renal disease drugs together with other items for this condition could improve efficiency by eliminating the financial incentive to overuse separately billable drugs.⁴⁴ Furthermore, we have reported that the home health PPS, which involves paying home health agencies a single bundled payment per 60-day episode of care, provides strong financial incentives to reduce the cost of providing home health care.⁴⁵

Paying separately under Part B for ultrasound exams and associated equipment and ambulance transportation also would increase overall Medicare payments for these services unless the additional Part B expenditures were offset by payment reductions for other services. Congress chose to do this on a previous occasion. ⁴⁶ Thus, if Congress instituted separate Part B payments for ultrasound exams and associated equipment and ambulance transportation during Part A-covered SNF stays, these payments could possibly be made budget neutral by a reduction in the Part A PPS payment. However, making this policy budget neutral would require that the Part A PPS payment reduction account for the potential of increased service use associated with unbundling services.

⁴³Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy* (Washington, D.C.: March 1999).

⁴⁴See GAO, End-Stage Renal Disease: Bundling Medicare's Payment for Drugs with Payment for All ESRD Services Would Promote Efficiency and Clinical Flexibility, GAO-07-77 (Washington, D.C.: Nov. 13, 2006) and Medicare Payment Advisory Commission, Report to the Congress, Medicare Payment Policy (Washington, D.C.: Mar. 2001).

⁴⁵GAO, Medicare Home Health Care: Payments to Home Health Agencies Are Considerably Higher than Costs, GAO-02-663 (Washington, D.C.: May 6, 2002).

⁴⁶On the basis of recommendations from CMS, Congress mandated in the Balanced Budget Refinement Act of 1999 that Medicare pay separately under Part B for certain services (for example, chemotherapy and customized prosthetic devices) during Part A-covered SNF stays. See Pub. L. No. 106-113, div. B, § 1000(a)(6) [H.R. 3426, title I, sec. 103(a)], 113 Stat. 1501, 1536 and 1501A-325-326 (codified at 42 U.S.C. § 1395yy(e)(2)(A)(iii)). In doing so, Congress required that CMS reduce the Part A PPS payment to offset the increase in Part B expenditures resulting from paying separately for these services.

Evidence and
Variation in Federal
Requirements Are
Among Factors to
Consider in
Determining Whether
to Establish
Credentialing or
Other Qualification
Requirements for
Sonographers

Factors for CMS to consider in determining whether to establish credentialing or other qualification requirements for sonographers include findings about the value of credentialing from peer-reviewed studies, MedPAC, and ultrasound-related organizations, coupled with variation in federal requirements and lack of state requirements for sonographers. Options available to CMS for promoting the quality of ultrasound services include specifying sonographers' qualifications via a National Coverage Determination (NCD), promulgating a regulation, and offering a financial incentive for quality improvements through "pay for performance" mechanisms.

Studies and Professional Organizations Suggest that Setting Requirements for Sonographers' Qualifications Could Promote Quality

Sonographer qualifications play an important role in the quality and diagnostic usefulness of ultrasound procedures. Representatives from ultrasound-related professional organizations described ultrasound procedures as highly operator dependent. In addition, they noted that the accuracy and diagnostic usefulness of the images captured depends on the sonographer's skills and abilities. When conducting diagnostic ultrasound procedures, the sonographer is responsible for obtaining quality images of internal body parts to enable the physician to make correct diagnoses of patients' diseases and medical conditions. Two studies have shown that poor quality images can lead to misdiagnosis or unnecessarily repeated exams. 47 Representatives of some ultrasound-related professional organizations that we interviewed noted that the increased use of ultrasound procedures in clinical practice and sophistication of the equipment have heightened the need for sonographers to undergo formal training. Currently, about 50 to 60 percent of the sonographers have the appropriate credentials, according to ARDMS estimates.

⁴⁷See D. G. Stanley, "The Importance of Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL) Certification for Noninvasive Peripheral Vascular Tests: The Tennessee Experience," *The Journal for Vascular Ultrasound*, vol. 28, no. 2 (2004) and O. William Brown, et al., "Reliability of Extracranial Cartoid Artery Duplex Ultrasound Scanning: Value of Vascular Laboratory Accreditation," *Journal of Vascular Surgery*, vol. 39, no. 2 (2004).

While studies that demonstrate the need for credentialing and accreditation have been limited in number and scope, those that exist seem to suggest that imposing credentialing or other qualifications on sonographers can improve the accuracy of ultrasound procedures. For example, two of the four relevant peer-reviewed studies from our literature review found that the results of noninvasive vascular ultrasound exams done by accredited facilities were more accurate than those exams by nonaccredited facilities. The authors of these studies emphasized the importance of accurate ultrasound exams for clinical decisions that vascular surgeons make about patient treatment.

Medicare experience with another type of imaging—mammography—also suggests that establishing federal standards that include requirements for personnel qualifications and facility accreditation could improve quality. In contrast to diagnostic ultrasound procedures, the Food and Drug Administration (FDA) established and enforces national quality standards for mammography services, which appear to have improved the quality of these procedures. Among other provisions in these standards, FDA established qualifications and continuing training requirements for mammography personnel, such as radiological technologists who perform the examinations, and also required facility accreditation. We previously reported that these quality standards, in conjunction with state inspection

⁴⁸See appendix IV for summaries of the studies discussed in this section.

⁴⁹See D. G. Stanley, "The Importance of Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL) Certification for Noninvasive Peripheral Vascular Tests: The Tennessee Experience," p. 1, and O. William Brown, et al., "Reliability of Extracranial Cartoid artery duplex Ultrasound scanning: Value of vascular laboratory accreditation," p. 369.

 $^{^{50}\}mbox{Mammography}$ is an X-ray imaging procedure that can detect small tumors and breast abnormalities.

⁵¹The Mammography Quality Standards Act of 1992, Pub. L. No. 102-539, § 2, 106 Stat. 3547, 3547-61 amended by the Mammography Quality Standards Reauthorization Acts of 1998 and 2004, Pub. L. No. 105-248, §§ 2-13, 112 Stat. 1864, 1864-67, Pub. L. No. 108-365, §§ 2-4, 118 Stat. 1738, 1738-40, respectively, required that the HHS establish these standards.

⁵²FDA regulations also specify detailed requirements for qualifications and continuing training for physicians who interpret the images and for mammography equipment and recordkeeping practices. See 21 C.F.R. § 900.12 (2006).

programs, have increased mammography facilities' adherence to accepted quality assurance standards and improved the quality of X-ray images. 53

Furthermore, MedPAC and various ultrasound-related professional organizations with which we spoke support the implementation of a Medicare policy establishing requirements for the qualifications of sonographers. MedPAC recommended in 2005 that CMS "strongly consider" establishing standards for providers that perform and bill for imaging exams, which include diagnostic ultrasound procedures. MedPAC noted that these standards should address the qualifications of the performing technicians in addition to other aspects of imaging procedures. In addition, representatives from 11 ultrasound-related professional organizations support establishing requirements concerning sonographers' qualifications through sonographer credentialing and facility accreditation. (See app. V for a list of these organizations.) Of these 11 organizations, 4 are ultrasound-related medical societies that do not credential sonographers or accredit facilities that conduct ultrasound procedures and the remaining 7 do.

Representatives from these organizations said that to conduct diagnostic ultrasounds, sonographers need to be trained and have broad knowledge, good judgment, and discretion. Representatives from the Society for

⁵³See GAO, Mammography Services: Impact of Federal Legislation on Quality, Access, and Health Outcomes, GAO/HEHS-98-11 (Washington, D.C.: Oct. 21, 1997); Mammography Quality Standards Act: X-ray Quality Improved, Access Unaffected, but Impact on Health Outcomes Unknown, GAO/HEHS-98-164 (Washington, D.C.: May 8, 1998; Mammography Services: Initial Impact of New Federal Law Has Been Positive, GAO/HEHS-96-17 (Washington, D.C.: Oct. 27, 1995); and Mammography: Current Nationwide Capacity Is Adequate, but Access Problems May Exist in Certain Locations, GAO-06-724 (Washington, D.C.: July 25, 2006).

⁵⁴MedPAC also recommended that the Secretary of HHS select private organizations to administer these standards, and noted that CMS has similar "deeming" arrangements with private accreditation groups for several types of providers, such as hospitals and ambulatory surgical centers." See Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy* (Washington, D.C.: Mar. 2005).

⁵⁵MedPAC (2005) noted the following with regard to imaging services, which include ultrasound procedures: "CMS should strongly consider setting standards for at least the following areas: the imaging equipment, qualifications of technicians, qualifications and responsibilities of the supervising physician, technical quality of the images produced, and procedures for ensuring patient safety (for example, monitoring radiation exposure)."

⁵⁶These four organizations were the American Society of Echocardiography, the Society of Diagnostic Medical Sonography, the Society for Vascular Surgery, and the Society for Vascular Ultrasound. See appendix V for descriptions of these organizations.

Vascular Surgery stated that, because some procedures were done by inadequately trained technical staff or by facilities with little or no quality control, there are a "disturbing number" of patients who have (1) missed or delayed treatment of major health issues or (2) undergone unnecessary treatment due to abnormal results being classified normal or normal results being classified as abnormal. An article in a peer-reviewed journal reported that 91 percent of members of the Society for Vascular Ultrasound and the Society of Diagnostic Medical Sonography agreed that adding requirements for sonographer credentialing and facility accreditation would improve the quality of vascular ultrasound procedures.⁵⁷

Some representatives of ultrasound equipment manufacturers and mobile ultrasound providers we interviewed also generally support sonographer credentialing. However, two of the manufacturer-related organizations we contacted and one provider were concerned that requirements for credentialing or accreditation could result in significant shortages of sonographers. Representatives from these manufacturer-related organizations noted that a phase-in period for establishing new requirements for sonographers would help prevent any potential access problems. Similarly, representatives of ultrasound-related professional organizations that we interviewed emphasized the importance of a phase-in period to allow time for sonographers to become credentialed.

Federal Requirements for Sonographers' Qualifications Vary and State Requirements Are Absent

Federal requirements relating to the qualifications of sonographers are inconsistent. This variation calls into question whether all sonographers paid by Medicare have appropriate and sufficient skills, knowledge, and experience to serve beneficiaries. Variation in federal requirements is also more of a concern because none of the states require that sonographers register or obtain a license from the state prior to providing ultrasound services, according to ultrasound-related professional organizations. At the federal level, CMS has not developed a national policy, such as an NCD, regarding the qualifications needed by sonographers as a condition for payment of ultrasound services. In the absence of an NCD for sonographers' qualifications, carriers have established Local Coverage

⁵⁷See S. Boswell et al., "Practice Patterns and Membership Opinion About the Value of Credentialing and Accreditation: Results of a Membership Survey," *Journal of Diagnostic Medical Sonography*, vol. 19, no. 6 (2003), p. 390.

Determinations (LCD) for different types of diagnostic ultrasound procedures.

Allowing carriers to develop their own LCDs has resulted in varying Medicare requirements in different states for sonographers who perform particular types of diagnostic ultrasound procedures.⁵⁸ For example, as of April 2007, carriers in 24 states and the District of Columbia have established one or more LCDs that require that noninvasive vascular diagnostic ultrasound procedures be performed by a credentialed sonographer (one that has undergone a certification process) or in an accredited facility that may require sonographers to meet certain qualification requirements.⁵⁹ Carriers' rationale was that the quality of these ultrasound procedures depends on the knowledge, skill, and experience of the sonographer. Carriers in 17 states have LCDs that recommend that noninvasive vascular diagnostic ultrasound procedures be performed by a credentialed sonographer or in an accredited facility. However, in the remaining 9 states, Medicare carriers have not established requirements through an LCD specifying the qualifications for sonographers who conduct noninvasive vascular ultrasound procedures. (See fig. 3.) Regarding mandatory requirements, a 2003 study that discussed reasons influencing a provider's decision to obtain facility accreditation in vascular ultrasound cited a 1998 study that found that

⁵⁸In 2003, we reported that giving Medicare contractors broad discretion to make local coverage policies had led to inequitable variations in coverage for beneficiaries depending on where they were treated. We recommended that CMS develop and implement a plan to evaluate the merits of existing coverage policies with the intent of incorporating appropriate aspects of local policies into national coverage policies and eliminating the remainder. See GAO Medicare: *Divided Authority for Policies on Coverage of Procedures and Devices Results in Inequities*, GAO-03-175 (Washington, D.C.: Apr. 11, 2003). CMS has implemented a policy to consider and address policy variations, but the agency has not considered developing an NCD concerning sonographers' qualifications.

⁵⁹Accredited facilities may require that sonographers have certain credentials or a combination of formal training and experience.

providers are more likely to seek facility accreditation when it is required for Medicare payment. ⁶⁰ The 2003 study noted that "alternatives that consider voluntary compliance to ultrasound standards may be unsuccessful." ⁶¹

⁶⁰Among the other reasons that providers gave for obtaining facility accreditation was the expectation that CMS would develop such a requirement and providers' own interest in meeting medical practice standards. In contrast, some providers cited difficulty in meeting technical requirements, lack of staff or time resources, and expensive application fees as a reason not to seek facility accreditation. The information about these reasons is based on a pilot study that the author conducted in 1998. See Kathleen M. Wilson, *The Emergence and Fall of the Ultrasound Quality Standards Act (H.R. 4217): Exploring the Interaction of Policy and Politics*. Unpublished doctoral dissertation, University of Maryland, Baltimore County, Baltimore, Md. (2003), p. 18.

 $^{^{61}\!\}text{See}$ Kathleen M. Wilson, The Emergence and Fall of the Ultrasound Quality Standards Act, p. 21.



Figure 3: Medicare Carriers' Part B LCDs on Noninvasive Vascular Diagnostic Ultrasound Procedures, as of April 2007

Sources: GAO analysis of carriers' Part B local coverage determinations concerning noninvasive vascular diagnostic ultrasound procedures and echocardiography. Copyright © Corel Corp. All rights reserved (map).

^aThe Medicare carrier in Queens, N.Y., does not have an LCD that includes a recommendation or requirement that noninvasive vascular diagnostic ultrasound procedures be performed by a credentialed sonographer or in an accredited laboratory.

There is also variation in LCDs concerning diagnostic ultrasound procedures used to diagnose heart and other conditions. While carriers in 12 states had developed LCDs as of April 2007 that require that these procedures be performed by a credentialed sonographer or in an accredited laboratory and carriers in 4 states had LCDs that recommended these types of qualifications for sonographers, the remaining states and the District of Columbia have no such LCDs. Finally, as of September 2006, carriers in 4 states had LCDs that established qualification requirements for sonographers that perform certain other diagnostic ultrasound procedures, such as abdominal and pelvic ultrasound. However, there are no similar LCDs in the remaining states and the District of Columbia.

Variations in Medicare requirements regarding sonographers' qualifications also relate to the sites of service where diagnostic ultrasound procedures are performed. For example, CMS has developed standards for nonphysician personnel that could be applicable to sonographers who perform diagnostic ultrasound procedures in independent diagnostic testing facilities (IDTF), but has not done so for physicians' offices. For IDTFs, CMS requirements specify that nonphysician personnel, including sonographers, who perform diagnostic ultrasound procedures, must demonstrate the basic qualifications to perform those procedures and have appropriate training and proficiency. To meet this requirement, in the absence of a state licensing board, sonographers must be credentialed by an appropriate national credentialing body. ⁶² Furthermore, the IDTF must maintain documentation available for review that Medicare credentialing requirements are being met.

Although there are no Medicare standards specifically related to the qualifications of sonographers working in hospitals, Medicare providers need to abide by the relevant Medicare Conditions of Participation (CoP), some of which appear to be applicable to the performance of ultrasound procedures. There are CoP provisions that include specific standards for medical staff and for radiology, huclear medicine, and outpatient services. According to the Medicare CoP for medical staff, hospitals are

⁶²See 42 C.F.R. § 410.33(c) (2006).

⁶³CMS's Conditions of Participation are requirements that health care organizations must meet in order to begin, and continue, participating in the Medicare program.

 $^{^{64}\!}A$ CMS official told us that diagnostic ultrasound procedures are typically provided in hospitals' radiology departments.

responsible for the quality of medical care provided to patients and must examine the qualifications and credentials of applicants for medical staff positions. If the hospital provides outpatient services, the CoP also requires that services must meet the needs of the patients in "accordance with acceptable standards of practice." Further, hospital outpatient departments are required to have appropriate professional and nonprofessional personnel available. In 2003, over 80 percent of hospitals met the applicable conditions of participation through accreditation from the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission)—a nonprofit organization created to provide voluntary health care accreditation for hospitals. ⁶⁵

In contrast to IDTFs and hospitals, there are no Medicare standards that apply specifically to diagnostic ultrasound procedures conducted in physicians' offices aside from those relating to the level of physician supervision required. The absence of qualification standards for sonographers working in physicians' offices is of particular interest given MedPAC and the Lewin Group's findings that there has been an increasing movement of imaging services, including ultrasound, from hospitals to physicians' offices. ⁶⁶

CMS Has Several Implementation Options

Several options are available to CMS for promoting the quality of diagnostic ultrasound procedures. Maintaining the status quo certainly imposes the least administrative burden and additional costs. However, this approach will not address the inconsistencies in requirements for sonographers' qualifications. We present three options for promoting the quality of ultrasound procedures, with associated potential benefits and challenges.

One option would be to develop an NCD requiring that sonographers either be credentialed or work in an accredited facility. Because NCDs apply to all Medicare beneficiaries regardless of their treatment locations,

⁶⁵Hospitals may also apply to CMS for a review of their compliance with CoP, or through accreditation from the American Osteopathic Association, as an alternative to accreditation by the Joint Commission. CMS's review is typically conducted by a state agency under contract with CMS.

⁶⁶See Medicare Payment Advisory Commission (MedPAC), Report to the Congress, Medicare Payment Policy (March 2005), p. 154 and Lane Koenig et al, Lewin Group, An Analysis of the Use of Ultrasound Imaging Services in the Medicare Program, pp. 19-20 (Washington, D.C.: 2005).

an NCD would provide a more consistent level of assurance as to the qualifications of sonographers performing diagnostic ultrasound procedures. However, under the NCD option, CMS indicated it would have to implement the sonographer qualification requirements immediately rather than gradually over a period of time, according to a CMS official. This time constraint could be problematic given that representatives of various ultrasound-related societies and organizations we interviewed generally suggested a phase-in period of 2 or more years to allow noncredentialed sonographers time to comply with the newly imposed requirements. Finally, establishing an NCD could be difficult, according to the CMS official, if it limited access to services for some beneficiaries, such as for those that lived in locations where no credentialed sonographer was readily available.

A second option would be to issue a regulation that establishes a requirement that sonographers either be credentialed or work in an accredited facility as a condition for Medicare payment. Such a regulation could be phased in over 2 or more years, which as noted by representatives of ultrasound-related professional organizations we interviewed, would allow noncredentialed sonographers time to comply with this requirement. A CMS official noted that the regulatory process would allow CMS to use a phase-in period for establishing such a requirement but that developing regulations can be burdensome and time consuming for CMS.

A third option would be for CMS to explore the possibility of "paying for performance" to encourage quality in the provision of diagnostic ultrasound procedures. CMS has recognized that the current Medicare reimbursement structure does not target resources to support specific efforts to provide the highest quality care. To address this shortcoming, CMS has initiated a number of demonstration and pilot projects, several required by Congress under statute, aimed at encouraging quality care and designed to lay the groundwork for pay-for-performance systems in the

⁶⁷The CMS official explained that because Medicare pays for services that are reasonable and necessary, if clinical evidence supported the need for an NCD relating to qualification requirements for sonographers, CMS would not be in a position to allow a phase-in period.

future. However, these pay-for-performance efforts are in the early stages of development, and none of them is focused on imaging services or diagnostic ultrasound procedures. A CMS official and representatives of various ultrasound-related professional organizations told us that it is difficult to develop clear and valid quality measures that could be applied to the performance of sonographers that conduct diagnostic ultrasound procedures.

Conclusions

We did not find compelling clinical or financial evidence in favor of providing Part B payments for ultrasound equipment transportation in addition to those for the exams themselves, for beneficiaries in noncovered SNF stays. While testimonial evidence suggests that there may be benefits of performing ultrasound exams in SNFs for some beneficiaries as opposed to transporting them to other locations, we could not locate any studies documenting this. Furthermore, our analysis suggests that Part B payments for ultrasound equipment transportation could increase Medicare expenditures and beneficiary cost sharing. In addition, paying separately under Part B for ultrasound exams and associated equipment and ambulance transportation during Part Acovered SNF stays would undermine the financial incentive of the PPS for SNFs to deliver these services efficiently. Paying separately under Part B for these services would also increase overall Medicare expenditures unless Congress made these additional Part B payments budget-neutral by reducing the Part A PPS payment.

As a national program affecting over 42 million beneficiaries, Medicare has a responsibility to ensure that the services it covers are of consistently high quality. Our findings from peer-reviewed studies and MedPAC and ultrasound-related professional organizations, coupled with our analysis of the variation in current requirements for sonographers, suggest that establishing requirements for sonographers' qualifications could improve the quality of ultrasound procedures. Maintaining the status quo of allowing Medicare carriers to have different requirements for sonographer qualifications in different states undermines the assurance that

⁶⁸For example, CMS has recently begun to implement the Medicare health quality demonstration, which is a 5-year program designed to achieve a number of goals, including enhancing quality, improving patient safety, and increasing efficiency. In addition, CMS is coordinating with a number of stakeholders, including physicians, to develop and implement uniform, standardized sets of performance measures for various health care settings.

beneficiaries are receiving consistently high-quality services. CMS has several available implementation options including developing a National Coverage Determination and promulgating regulations.

Recommendation for Executive Action

We recommend that the Administrator of CMS require that sonographers paid by Medicare either be credentialed or work in an accredited facility. The Administrator should weigh the advantages and disadvantages of implementing a National Coverage Determination compared with promulgating regulations that this requirement be a condition for Medicare payment.

Agency Comments and Our Evaluation

In written comments on a draft of this report, CMS stated that while it would consider our recommendation to require that sonographers furnishing services to Medicare beneficiaries either be credentialed or work in an accredited facility, it would rather have states engage their own licensing bodies in implementing sonographer licensure programs that address competency and qualification issues. We reprinted CMS's written comments in appendix VI.

CMS characterized our recommendation as providing two options issuing an NCD or promulgating a regulation establishing sonographer qualifications as a Condition of Participation—and stated that these options do not provide the most effective mechanism for addressing sonographer quality. We noted in our report that issuing a regulation was an option for CMS. However, we did not specify that this regulation apply only to ultrasound services furnished in or by providers that are subject to Conditions of Participation (generally, institutional providers, such as hospitals) because we believe it is important that sonographer qualification requirements apply to all sonographers, regardless of the setting in which they provide the service, including physicians' offices. CMS agreed with our finding that sonographer qualification requirements vary but stated that a national policy would not take into account regional variation in factors such as access to care and state licensing requirements. We agree that access is an important issue when considering whether to implement an NCD or a regulation, and we pointed out that such a regulation could include a phase-in period to provide noncredentialed sonographers with time to comply with the newly imposed requirements. Furthermore, although CMS asserted that states should engage their own licensure bodies to implement sonographer licensure programs, we reported that state licensing requirements for sonographers do not exist. Consequently, we continue to believe that CMS

should implement our recommendation and develop a national policy establishing sonographer qualification requirements. Such requirements, that sonographers paid by Medicare either be credentialed or work in an accredited facility, would help to promote the quality of ultrasound procedures across states and sites of service where consistent policy is currently lacking.

CMS agreed with our conclusion that paying separately under Part B for ultrasound exams and associated equipment and ambulance transportation would undermine the financial incentive for SNFs to deliver these services efficiently. CMS further noted that paying separately for ultrasound exams could potentially lead to doing so for other services and lead to the "unraveling" of the SNF PPS bundle.

We are sending copies of this report to the Administrator of CMS, appropriate congressional committees, and other interested parties. We will also provide copies to others on request. In addition, this report is available at no charge on the GAO Web site at http://www.gao.gov.

If you or your staff have questions about this report, please contact me at (202) 512-7114 or steinwalda@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff members who made contributions to this report are listed in appendix VII.

Bu Tulp

A. Bruce Steinwald Director, Health Care

Appendix I: Scope and Methodology

This appendix explains the methodology that we used to address our reporting objectives on (1) the types of ultrasound procedures commonly used to diagnose medical conditions of Medicare beneficiaries, particularly those in skilled nursing facilities (SNF); (2) the financial impact of changing how Medicare pays for ultrasound exams and associated equipment and ambulance transportation for beneficiaries receiving care in a SNF; and (3) the factors to consider in determining whether the Centers for Medicare & Medicaid Services (CMS) should establish credentialing or other qualification requirements for sonographers that provide diagnostic ultrasound procedures.

Types of Ultrasound Procedures Provided to Beneficiaries

To examine the types of diagnostic ultrasound procedures provided to Medicare beneficiaries, medical conditions that were diagnosed, and sites of service where these procedures were performed, we analyzed Medicare claims for ultrasound procedures paid under Part B in 2005. These data came from the National Claims History (NCH) carrier file and the Standard Analytical File (SAF) outpatient claims files. We based our analysis of the types of procedures on claims for physicians' interpretations of ultrasound exams, which account for procedures provided to all beneficiaries because all physicians' interpretations of ultrasound exams are paid under Part B, regardless of whether the exam itself was paid under Part A or Part B. We based our analysis of the site of service of ultrasound procedures on claims for ultrasound exams that were paid under Part B.² Therefore, our site of service analysis does not cover exams for beneficiaries in Part A-covered SNF and hospital inpatient stays because Part A payment for these exams is bundled with other services and thus not separately reported in claims data.

To identify the specific diagnostic ultrasound procedures to analyze, we performed several steps. We began by developing a list of all the relevant diagnostic ultrasound procedures using information from the 2005 American Medical Association (AMA) Current Procedural Terminology

¹In this analysis of the types of ultrasound procedures, we also included claims for ultrasound procedures classified solely as physician services that do not include a separately billed exam and physician's interpretation of it.

²The Medicare Part B claims for ultrasound exam allowed us to identify the site of service where the sonographers produced the actual image. In this analysis of the site of service of ultrasound exams, we also included claims for ultrasound procedures classified solely as physician services that do not include a separately billed exam and physician's interpretation of it.

(CPT) guide, and interviews with a credentialed sonographer with particular expertise in ultrasound coding and billing issues, and CMS officials, as well as documents provided during these interviews. We also reviewed the CMS Berenson-Eggers Type of Service (BETOS) codes, which categorize Healthcare Common Procedure Coding System (HCPCS) codes into clinically relevant categories. For this report, we selected 94 HCPCS codes in the BETOS categories for echography, which is a synonym for ultrasound. We then supplemented these 94 codes with 10 additional ones that we identified based on our review of codes in the AMA CPT Guide for 2005. The 104 total HCPCS codes we selected accounted for approximately 99 percent of all Medicare Part B payments for diagnostic ultrasound procedures in 2005.

To analyze sites of service where ultrasound procedures were performed, we used Medicare data from the 2005 NCH carrier and SAF outpatient claims files. In addition, we used data and reviewed regulations from CMS on the appropriate level of physician supervision for each ultrasound procedure to examine how supervision levels varied across sites of service.⁶

³HCPCS is a standardized classification method used by CMS to identify medical, including ultrasound, services and procedures. It is used in the submission to Medicare and other insurers of claims for payment of services rendered by physicians and other providers.

⁴The six BETOS echography categories used to group HCPCS codes are as follows: (1) eye (category I3A), (2) abdomen/pelvis (category I3B), (3) heart (category I3C), (4) carotid arteries (category I3D), (5) prostate, transrectal (category I3E), and (6) other (category I3F).

⁵We supplemented the HCPCS codes in the BETOS categories for echography rather than using all HCPCS codes for diagnostic ultrasound procedures for two reasons. First, we wanted to promote comparability with other studies that use the BETOS categories. Second, supplementing the HCPCS codes in the BETOS echography categories accounted for virtually all (99 percent) of Medicare Part B spending on diagnostic ultrasound procedures.

⁶CMS has established three levels of physician supervision for the technician who conducts the exam component of ultrasound procedures and other diagnostic tests. The first level involves general supervision, which means that the procedure must be provided under the physician's overall direction and control, but the physician's presence is not required while the technician performs the exam. The second level involves direct supervision in the office setting, which means that the physician must be present in the office suite and immediately available to furnish assistance and direction while the technician performs the exam. The third level involves personal supervision, which requires a physician to be in attendance in the room during the performance of the procedure. See appendix II for more detail.

To examine clinical considerations associated with site of service and to supplement our data analysis on the medical conditions, we conducted a literature search and structured interviews with representatives of gerontological, radiological, and ultrasound-related professional organizations. Key search terms included transition of care, which involves moving the beneficiary from the SNF to another facility for the purpose of performing an ultrasound procedure; transfer trauma; patient transfers; and risks and morbidity associated with the movement of elderly persons to different settings. For the structured interviews, we contacted representatives from the American Geriatrics Society, the American Medical Directors Association, the American College of Radiology, the American Society of Echocardiography, the Society for Vascular Surgery, and the Society for Vascular Ultrasound. In addition, we interviewed four mobile ultrasound providers that provide services to SNFs or nursing homes and representatives from the National Association for the Support of Long-Term Care and the American Association of Homes and Services for the Aging. We also conducted structured interviews with SNF directors of nursing in states selected based on criteria including their ultrasound use level per beneficiary.⁷

Financial Impact of Changing Payment Methods

We estimated the financial impact of two changes in Medicare payment methodology for ultrasound exams and associated equipment and ambulance transportation for beneficiaries receiving care in a SNF. The first change we addressed was to make payments to transport and set up ultrasound equipment for exams conducted in SNFs during noncovered SNF stays, which is not currently done. The second change involved paying separately under Part B for ultrasound exams and associated equipment and ambulance transportation during Part A-covered SNF stays.

Paying to Transport and Set Up Ultrasound Equipment

To estimate the financial impact of this potential change, we used Medicare Part B claims data for 2005 for ultrasound exams and ambulance services from the NCH carrier and SAF outpatient files. Based on these data, we (1) identified the number of exams conducted in SNFs during noncovered SNF stays, in beneficiaries' homes, or in custodial care or

⁷We obtained information from four directors of nursing in four states: Connecticut, Florida, New York and Pennsylvania.

assisted living facilities,⁸ (2) determined the number of beneficiary days on which these exams were conducted,⁹ and (3) multiplied the number of beneficiary days by our estimate of the average Medicare payment and beneficiary cost sharing for ultrasound equipment transportation, both including and excluding the equipment set-up fee, in the Medicare locality where the claim was processed.¹⁰ Through these steps, we estimated how the expenditures of Medicare and its beneficiaries would have differed if Medicare had paid to transport and set up ultrasound equipment in 2005, assuming that the number and location of exams would not have changed in response to this policy. (See app. III, table 7.)

To gain insight into how Medicare payments to transport and set up ultrasound equipment would affect the number of ultrasound exams in SNFs during noncovered SNF stays, we used information from interviews and two types of analyses. First, we interviewed representatives of four mobile ultrasound providers. Second, we analyzed Part B claims data from the Part B Extract Summary System for 1995, when Medicare contractors in some states paid to transport and set up ultrasound equipment, and 1997, when these payments were no longer provided. We compared the change between 1995 and 1997 in the number of ultrasound exams conducted in SNFs in 14 states that provided these payments in 1995 to the same measure in the remaining states that did not provide such

⁸The number of exams includes ultrasound procedures classified solely as physician services that do not include a separately billed exam. To identify exams conducted in SNFs during noncovered SNF stays, we first selected all Part B claims for ultrasound exams that were conducted in a SNF or nursing facility and then, based on claims for Part A-covered SNF stays, we omitted those that were billed during Part A-covered SNF stays.

⁹The number of beneficiary days is defined as the sum across all beneficiaries in a given site of service of the number of days on which ultrasound exams occurred for each beneficiary. For example, if a beneficiary received at least one ultrasound exam on 2 separate days, this beneficiary would contribute 2 beneficiary days to the total.

¹⁰We based our estimate of the average Medicare payment and beneficiary cost sharing for ultrasound equipment transportation on the same measures for a similar service—the transportation and set-up fees for portable x-ray equipment transportation in 2005.

¹¹Carriers in the following 14 states provided these payments in 1995: Arizona, Connecticut, Delaware, Georgia, Iowa, Maine, Maryland, Massachusetts, Missouri, Nevada, New Hampshire, New Jersey, Pennsylvania, and Vermont. Transportation payments were also made in Northern California, but not in the southern part of that state.

payments.¹² (See app. III, table 8.) Third, we analyzed Part B claims data for ambulance services that appear to have been used in conjunction with ultrasound exams.

If there was a decline in the number of ultrasound exams in SNFs during noncovered SNF stays in response to Medicare payments to transport and set up ultrasound equipment, it could cause the site of service of some exams to shift from these locations to other sites of service (such as a hospital outpatient facility). To determine whether this change in site of service would increase or decrease our impact estimates for paying to transport and set up ultrasound equipment, we accounted for how this change would affect Medicare expenditures and beneficiary cost sharing for (1) ambulance transportation, ¹³ (2) the transportation and set up of ultrasound equipment, and (3) the ultrasound exam.

Some ultrasound exams conducted during noncovered SNF stays may require ambulance services to transport the beneficiary to another location, such as a hospital outpatient facility, for the exam. To estimate how Medicare payments and beneficiary cost sharing would have differed in 2005 if these exams had instead been conducted in SNFs during noncovered SNF stays, ¹⁴ we first identified ambulance trips used to transport these beneficiaries from SNFs to another location for an ultrasound procedure. ¹⁵ We then calculated how Medicare payments and beneficiary cost sharing for the ultrasound exam and associated transportation would have differed if, rather than transporting the beneficiary via ambulance to another location, ultrasound equipment had

¹²We excluded California from our analysis because the policy regarding payments for ultrasound equipment transportation and set up was not consistent throughout the state. For this analysis, we defined ultrasound exams as HCPCS codes in the BETOS categories for echography and included exams in both SNFs and nursing facilities.

¹³On the basis of our earlier work, we estimated that 40 percent of beneficiaries who received an ultrasound exam in a nursing home would need to be transported via ambulance if the exam were conducted at another site of service, such as a hospital outpatient facility. See GAO/HEHS-98-82.

¹⁴To identify beneficiaries in noncovered SNF stays, we first used the origin and destination of the ambulance trips to determine whether a beneficiary was in a SNF stay and then omitted any beneficiary whose ultrasound exam, based on the SNF claims, occurred during a Part A-covered SNF stay.

¹⁵Ambulance trips for these beneficiaries (1) were on the same day as their ultrasound exam, which was not conducted in a SNF during a noncovered SNF stay and (2) transported a beneficiary from a SNF to a physician's office, hospital, or diagnostic or therapeutic site (for example, an independent diagnostic testing facility) and back.

been transported to the SNF for the exam. To estimate how conducting the exam in a SNF during a noncovered SNF stay rather than in another location would have affected Medicare payments and beneficiary cost sharing for transportation, we (1) calculated the number of beneficiary days on which these exams occurred, (2) determined the savings to Medicare and its beneficiaries per beneficiary day if, instead of transporting a beneficiary via ambulance to another location, ultrasound equipment were transported to the beneficiary for the exam, by subtracting our estimate of the ultrasound equipment transportation payment and cost-sharing amounts for each beneficiary day from the actual payment for ambulance services, and (3) multiplied this difference by the number of beneficiary days. To estimate the savings to Medicare and its beneficiaries for the exam itself, we subtracted the cost of conducting all of these exams in a SNF during noncovered SNF stays from the actual cost of these exams.

The key limitation of our analysis of the financial impact of paying to transport and set up ultrasound equipment involves the accuracy of our assumption that this policy would not affect the number and location of ultrasound exams in SNFs during noncovered SNF stays. Therefore, to address the possibility that this policy change could affect ultrasound service use, we analyzed how such a change could affect our impact estimates.

Paying Separately under Part B for Ultrasound Exams and Related Transportation during Part A-Covered SNF Stavs

To estimate the financial impact of paying separately under Part B for ultrasound exams and associated equipment and ambulance transportation during Part A-covered SNF stays, we analyzed claims for ultrasound exams and physicians' interpretations of them for beneficiaries in Part A-covered SNF stays from Medicare Part B claims data for 2005 from the NCH carrier file and the SAF outpatient claims files. We first counted the number of physicians' interpretations of ultrasound exams that were conducted during Part A-covered SNF stays in 2005. We merged Part B claims for physicians' interpretations of ultrasound exams in 2005 with SNF claims for the same year to determine which interpretations occurred during Part A-covered SNF stays. We then multiplied the number of physician interpretations of each exam by the average Medicare

payment and beneficiary cost-sharing amounts for the corresponding exam.¹⁶

Ultrasound exams and other services are bundled into the SNF prospective payment system (PPS) rate for beneficiaries in Part A-covered SNF stays, so Medicare should not pay separately under Part B for these exams. However, we identified claims for up to 33,000 ultrasound exams conducted during Part A-covered SNF stays as having been improperly billed. Medicare paid approximately \$2.6 million for these exams, and beneficiaries paid about \$1.5 million. If Medicare contractors did not recoup all of these improper payments as they are required to, then our estimate of the financial impact of paying separately under Part B for ultrasound exams would be overstated because Medicare would have already been paying separately under Part B for some of these exams in the absence of this policy. However, because data for improperly paid claims do not indicate whether the payments were recouped, we were unable to accurately estimate the extent to which these improper payments affect our estimates.

To estimate the financial impact of paying separately under Part B for ultrasound equipment transportation for beneficiaries in Part A-covered SNF stays, we first estimated the number of ultrasound exams conducted

¹⁶The average Medicare payment and beneficiary cost-sharing amounts for each HCPCS code were calculated based on Part B claims for ultrasound exams for all Medicare beneficiaries in 2005. Estimates for this analysis may slightly overstate the actual financial impact of separate Part B payments for ultrasound exams and associated equipment and ambulance transportation because up to 5 percent of ultrasound exams conducted during Part A-covered SNF stays were on beneficiaries in critical access hospitals that may have been certified as swing bed hospitals, which were not subject to the PPS.

¹⁷The actual number of improperly paid exams and associated Medicare payments and beneficiary cost sharing may be slightly lower than these estimates because up to 3 percent of these exams may have been conducted on beneficiaries in Part A-covered SNF stays who were in critical access hospitals that were certified as swing bed hospitals, which were not subject to the PPS.

¹⁸The Office of Inspector General (OIG) of HHS is currently addressing the issue of improper billing for beneficiaries in Part A-covered SNF stays. For previous OIG reports on this issue, see HHS OIG, Review of Improper Payments Made by Medicare Part B for Services Covered Under the Part A Skilled Nursing Facility Prospective Payment System in Calendar Years 1999 and 2000, A-01-02-00513 (Washington, D.C.: May 2004); Review of Potential Improper Payments Made by Medicare Part B for Services Covered Under the Part A Skilled Nursing Facility Prospective Payment System, A-01-00-00538 (Washington, D.C.: June 2001); and Review of Compliance with the Consolidated Billing Provision Under the Prospective Payment System for Skilled Nursing Facilities, A-01-99-00531 (Washington, D.C.: March 2000).

in SNFs, as opposed to other sites of service, for these beneficiaries in 2005. To do so, we multiplied the number of physician interpretations of exams for these beneficiaries in that year by the proportion of all ultrasound exams for the same population in 1997 that were conducted in SNFs. We converted this estimate of the number of exams done in SNFs for these beneficiaries into the number of beneficiary days to indicate how many equipment transportation and set-up fees Medicare would have paid. To calculate the financial impact on Medicare payments, we added the product of (1) the number of beneficiary days and the average estimated equipment transportation fee and (2) the number of exams and estimated average of the equipment set-up fee. To calculate the financial impact on beneficiary cost sharing, we added the product of (1) the number of beneficiary days and the average estimated cost sharing for equipment transportation and (2) the number of exams and average estimated equipment transportation fee. To calculate the financial equipment transportation and (2) the number of exams and average estimated equipment transportation fee.

We used a similar process to estimate the financial impact of separate Part B payments for ambulance services used during Part A-covered SNF stays to transport beneficiaries from a SNF to another location for an ultrasound exam and back. We (1) estimated the number of ultrasound exams for beneficiaries in Part A-covered SNF stays in 2005 that involved ambulance transportation, by multiplying the number of physician interpretations of exams for these beneficiaries in that year by the proportion of exams for the same population in 1997 that involved ambulance transportation; (2) converted this estimate of the number of exams involving ambulance transportation into the number of beneficiary days to indicate how many ambulance round trips Medicare would have

¹⁹Based on current payment policy for portable x-ray equipment transportation, when multiple exams occur on a single beneficiary day (that is, during a single session for a given beneficiary), only one equipment transportation payment is required, although a set-up fee is paid for each exam. To convert the number of ultrasound exams conducted in SNFs to beneficiary days, we divided the number by the average number of these exams per beneficiary day based on Part B claims for exams conducted for beneficiaries in Part A-covered SNF stays in 1997—the most recent year for which these data were reported separately for these beneficiaries.

²⁰As with the first component of our financial impact analysis, we based our estimate of the average Medicare payment and beneficiary cost sharing for ultrasound equipment transportation on the same measures for a similar service—the transportation and set-up fees for portable x-ray equipment in 2005.

paid;²¹ and (3) multiplied the number of beneficiary days by the average cost to Medicare and a beneficiary of an ambulance round trip. We also did a literature search to locate studies addressing the effect of the SNF PPS on the use of ultrasound and certain other imaging services. Key search terms included Medicare, skilled nursing facility, prospective payment system, ultrasound, imaging, X-ray, computed tomography, magnetic resonance imaging, and angiography.

Our analysis of the financial impact of paying separately under Part B for ultrasound exams and related transportation has two key limitations. First, because more recent information was unavailable, we used 1997 data to estimate the number of ultrasound exams conducted in SNFs or that involved ambulance transportation.²² Therefore, the precision of estimates of the financial impact of paying separately under Part B for these services is limited by the accuracy with which the results based on the 1997 data we used would have been similar if 2005 data had been available. In addition, the financial impact estimates we present are based on the assumption that service use would not change in response to this policy. To address the possibility that a policy of paying separately for services, as opposed to bundling payment for them, would affect the use of services, we (1) summarized studies we found that addressed how bundling payment for services can affect their use and (2) conducted a literature search to identify studies addressing how the use of certain imaging, and specifically ultrasound, services changed in response to the SNF PPS.

²¹To convert the number of ultrasound exams involving ambulance transportation to beneficiary days, we divided the number by the average number of these exams per beneficiary day based on Part B claims for exams conducted for beneficiaries in Part Acovered SNF stays in 1997.

²²Data from 1997 are the most recent available for which the exams' site of service was available for beneficiaries in Part A-covered SNF stays because, in 1998, CMS began phasing in the SNF PPS, which bundled payment for these and other services provided to beneficiaries in Part A-covered SNF stays.

Factors to Consider Concerning Sonographer Qualification Requirements

To identify factors to consider in determining whether CMS should establish credentialing or other qualification requirements for sonographers, we reviewed applicable Medicare regulations and CMS documents on Medicare coverage policies, including Medicare National Coverage Determinations. In addition, we reviewed Medicare carriers' Local Coverage Determinations (LCD) related to the qualification requirements for sonographers that perform echocardiograms, noninvasive vascular ultrasounds, and other diagnostic ultrasounds, such as abdominal and pelvic ultrasounds. To identify these coverage policies, we conducted searches in CMS's Medicare Coverage Database for draft and final LCDs related to echocardiograms and noninvasive vascular ultrasounds as of April 2007 for each Medicare carrier. We also conducted a search in CMS's Medicare Coverage Database for LCDs related to other diagnostic ultrasounds as of September 2006.

In addition, we interviewed CMS and Medicare Payment Advisory Commission officials and representatives from national organizations that award credentials in sonography or accredit facilities that perform ultrasound procedures, and reviewed documents that they provided to us. These organizations included the American Registry for Diagnostic Medical Sonography, the Intersocietal Accreditation Commission, the American Institute of Ultrasound in Medicine, Cardiovascular Credentialing International, and the American College of Radiology. Finally, we conducted a literature search and reviewed relevant studies in peer-reviewed journals.

Data Reliability

Medicare claims data, which are used by the Medicare program as a record of payments made to health care providers, are monitored by CMS. The data are subject to various checks and edits. Although we did not review these checks and edits, we assessed the reliability of the NCH data, which include all claims data analyzed for this report. We found the data sufficiently reliable for purposes of this report.

We performed our work from July 2006 through May 2007 in accordance with generally accepted government auditing standards.

²³The Intersocietal Accreditation Commission has five subgroups: the Intersocietal Commission for the Accreditation of Vascular Laboratories, the Intersocietal Commission for the Accreditation of Echocardiography Laboratories, the Intersocietal Commission for the Accreditation of Nuclear Medicine Laboratories, and the Intersocietal Commission for the Accreditation of Magnetic Resonance Laboratories.

Appendix II: Ultrasound Procedures and Medicare Part B Payments in 2005

This appendix contains information on the number of ultrasound procedures provided to Medicare beneficiaries in 2005 by site of service and the level of physician supervision required to administer the procedures. (See table 4.) This appendix also includes data on the five top medical conditions diagnosed by type of ultrasound procedures provided to Medicare beneficiaries overall and to those in SNF stays in 2005 that were not covered by Medicare. (See tables 5 and 6.)

Table 4: Number of Ultrasound Procedures Provided to Medicare Beneficiaries by Site of Service and Level of Physician Supervision Required, 2005

				Site of service		
Type of ultrasound procedure	Level of physiciansupervision required	Number of procedures ^a	Physician's office	Hospital outpatient department		Other ^c
Noninvasive vascular						
	General	6,347,815	3,821,749	2,376,169	69,704	80,193
Subtotal		6,347,815	3,821,749	2,376,169	69,704	80,193
Echocardiograms						
	General	12,698,357	9,517,262	3,065,385	28,655	87,055
	Direct	421,801	276,498	145,051	6	246
	Personal	77,040	3,507	51,842	30	21,661
	N/A ^d	1,008	5	1,003	0	0
Subtotal		13,198,206	9,797,272	3,263,281	28,691	108,962
Abdomen and pelvis						
	General	3,579,463	1,848,590	1,685,573	21,882	23,418
	Personal	24,523	13,489	10,924	0	110
Subtotal		3,603,986	1,862,079	1,696,497	21,882	23,528
Head, neck, and chest						
	General	1,907,810	1,295,574	603,117	1,853	7,266
	Direct	148,023	135,164	11,784	729	346
Subtotal		2,055,833	1,430,738	614,901	2,582	7,612
Ultrasonic guidance						
	General	454,230	248,076	199,252	0	6,902
	Personal	530,948	273,706	249,159	7	8,076
	N/A ^d	18,042	34	16,704	0	1,304
Subtotal		1,003,220	521,816	465,115	7	16,282

Appendix II: Ultrasound Procedures and Medicare Part B Payments in 2005

				Site of service		
Type of ultrasound procedure	Level of physiciansupervision required	Number of procedures ^a	Physician's office	Hospital outpatient department	Skilled nursing facility ^b	Other
Other diagnostic ultrasound	General	538,598	414,036	115,241	1,300	8,021
	Direct	21,220	10,857	10,051	0	312
	Personal	18,959	2,661	16,113	0	185
	N/A ^d	1,440,976	1,319,944	102,963	7,230	10,839
Subtotal		2,019,753	1,747,498	244,368	8,530	19,357
Total number of all procedures provided to beneficiaries		28,228,813	19,181,152	8,660,331	131,396	255,934

Source: GAO analysis of Medicare claims data for 2005 and Medicare regulations and policy guidance on the level of physician supervision required for diagnostic tests.

Notes: General supervision level means that the procedure is furnished under the physician's overall direction and control, but physician presence is not required during the performance of the procedure. This is the minimal level required for all diagnostic tests payable under the physician fee schedule, unless there are specific exceptions by regulation. Direct supervision means that the physician does not have to be present in the room when the procedure is performed, but the physician must be in the suite and be immediately available to furnish assistance throughout the procedure. Personal supervision means that the physician must be in attendance in the room during the performance of the procedure.

^aThe number of procedures is based on claims for ultrasound exams paid and claims for ultrasound procedures classified solely as physician services that do not include a separately billed exam and physician's interpretation of it.

^bWe counted the number of exams in skilled nursing facilities and nursing facilities.

Other includes (but is not limited to) home, independent laboratory, inpatient hospital, ambulatory surgical center, and emergency room.

^dN/A means not applicable.

Table 5: Top Five Medical Conditions Diagnosed by Type of Ultrasound Procedure Provided to Medicare Beneficiaries under Medicare Part B, 2005

Type of ultrasound procedure	Top five medical conditions diagnosed	Number of procedures	Percentage within procedure type
Noninvasive vascular			
	Occlusion and stenosis of precerebral arteries	1,661,280	20
	Other disorders of soft tissue	1,603,593	19
	Atherosclerosis	737,405	9
	Other peripheral vascular diseases	728,566	9
	Cardiovascular system problems	541,018	6
Subtotal top five		5,271,862	63
	Other noninvasive vascular	3,086,800	37
Total		8,358,662	100
Echocardiogram			
	Other diseases of endocardium	5,740,723	26
	Symptoms involving respiratory system and other chest symptoms	2,655,795	12
	Other forms of chronic ischemic heart disease	2,058,896	9
	Heart failure	2,054,101	9
	Cardiac dysrhythmias	1,375,924	6
Subtotal top five		13,885,439	64
	Other echocardiograms	7,947,756	36
Total		21,833,195	100
Abdomen and pelvis			
	Other symptoms involving abdomen and pelvis	1,340,438	27
	Other disorders of kidney and ureter	462,420	9
	Other disorders of urethra and urinary tract	263,473	5
	Cholelithiasis	242,872	5
	Symptoms involving urinary system	194,177	4
Subtotal top five		2,503,380	51
	Other abdomen and pelvis	2,425,031	49
Total		4,928,411	100
Head, neck, and, chest			
	Cataract	1,176,137	49
	Other disorders of breast	386,908	16
	Nontoxic nodular goiter	162,762	7
	Nonspecific abnormal findings on radiological and other examinations of body structure	146,047	6
	The second of th	1 10,017	

Appendix II: Ultrasound Procedures and Medicare Part B Payments in 2005

Type of ultrasound procedure	Top five medical conditions diagnosed	Number of procedures	Percentage within procedure type
	Benign mammary dysplasias	103,954	4
Subtotal top five		1,975,808	82
	Other head, neck, chest	438,042	18
Total		2,413,850	100
Ultrasonic guidance			
	Malignant neoplasm of prostate	229,242	18
	Nonspecific findings on examination of blood	150,046	12
	Other and unspecified aftercare	120,019	10
	Pleurisy	104,175	8
	Other symptoms involving abdomen and pelvis	84,506	7
Subtotal top five		687,988	55
	Other ultrasonic guidance	552,716	45
Total		1,240,704	100
Other diagnostic ultrasounds			
	Symptoms involving urinary system	836,940	40
	Hyperplasia	310,658	15
	Nonspecific findings on examination of blood	168,274	8
	Malignant neoplasm of prostate	93,512	4
	Other disorders of bladder	83120	4
Subtotal top five		1,492,504	70
	All other	626,456	30
Total		2,118,960	100
Total number of procedures provided to Medicare beneficiaries		40,893,782	

Source: GAO analysis of Medicare claims data for 2005.

Note: Percentages may not sum to 100 due to rounding. Our analysis is based on claims for physicians' interpretation of the exams and claims for ultrasound procedures classified solely as physician services that do not include a separately billed exam and physician's interpretation of it.

Table 6: Top Five Medical Conditions Diagnosed by Type of Ultrasound Procedure Provided in SNFs to Medicare Beneficiaries in Noncovered SNF stays and Paid Under Medicare Part B, 2005

Type of ultrasound procedure	Top five medical conditions diagnosed	Number of procedures	Percentage within procedure type
Noninvasive vascular			
	Other disorders of soft tissues	19,019	28
	Symptoms involving skin and other integumentary tissue	12,444	18
	Other peripheral vascular disease	10,876	16
	Phlebitis and thrombophlebitis	5,606	8
	Atherosclerosis	5,239	8
Subtotal top five		53,184	78
	Other noninvasive vascular	15,227	22
Total		68,411	100.00
Echocardiogram			
	Heart failure	7,943	28
	Other diseases of endocardium	3,763	13
	Cardiac dysrhythmias	2,884	10
	Symptoms involving Respiratory systems and other chest symptoms	2,669	9
	Diseases of mitral and aortic valves	1,623	6
Subtotal top five		18,882	66
	Other echocardiograms	9,571	34
Total		28,453	100.00
Abdomen and pelvis			
	Other symptoms involving abdomen and pelvis	10,450	48
	Other disorders of kidney and ureter	1,408	7
	Nonspecific abnormal results of function studies	1,314	6
	Other disorders of urethra and urinary tract	1,239	6
	Symptoms involving urinary system	1,081	5
Subtotal top five		15,492	72
	Other abdomen and pelvis	6,145	28
Total		21,637	100.00

Type of ultrasound procedure	Top five medical conditions diagnosed	Number of procedures	Percentage within procedure type
Head, neck, and chest		<u>-</u>	
	Cataract	889	35
	Other disorders of breast	244	10
	Other retinal disorders	218	9
	Simple and unspecified goiter	174	7
	Visual disturbances	120	5
Subtotal five		1,645	65
	Other	905	35
Total		2,550	100.00
Ultrasonic guidance			
	Nonspecific findings on examination of the blood	2	40
	Chronic renal failure	1	20
	Other disorders of soft tissue	1	20
	Organ or tissue replaced by transplant	1	20
Subtotal top four ^a		5	100.00
	Other	0	0
Total		5	100.00
Other diagnostic ultrasound			
	Symptoms involving urinary system	5,700	71
	Other disorders of bladder	676	8
	Other disorders of bone and cartilage	560	7
	Other disorders of male genital organs	188	2
	Symptoms involving skin and integumentary tissue	130	2
Subtotal top five		7,254	90
	Other	809	10
Total		8,063	100.00
Total number of procedures provided in SNFs to Medicare beneficiaries in noncovered SNF stays		129,119	100.00

Source: GAO analysis of Medicare claims data for 2005.

Note: Percentages may not sum to 100 due to rounding. Our analysis is based on claims for ultrasound exams and claims for ultrasound procedures classified solely as physician services that do not include a separately billed exam and physician's interpretation of it.

^aThere were only four medical conditions diagnosed by these five ultrasound guidance procedures.

Appendix III: Detailed Estimates of the Financial Impact of Changing Medicare Ultrasound Payment Methods

This appendix contains information on the financial impact of paying for ultrasound equipment transportation. (See table 7.) In addition, this appendix presents information on changes in the number of ultrasound exams conducted in skilled nursing facilities (SNF) between 1995 and 1997 (see table 8).

Table 7: Financial Impact of Ultrasound Equipment Transportation Payments, 2005

			• •	portation payment nly	Equipment transp up pay	
Site of service	Ultrasound exams (number)	Beneficiary days ^a (number)	Increase in Medicare payments (dollars)	Increase in beneficiary cost sharing (dollars)	Increase in Medicare payments (dollars)	Increase in beneficiary cost sharing (dollars)
Skilled nursing facilities ^b	129,119	83,591	8,477,240	2,262,706	9,786,084	2,636,868
Home	101,285	36,880	3,362,665	883,980	4,408,509	1,164,498
Custodial care facilities	17,490	7,900	837,061	218,101	1,007,215	264,314
Assisted living facilities	5,297	2,724	253,723	68,711	304,903	83,795
Total	253,191	131,095	12,930,690	3,433,498	15,506,711	4,149,475

Source: GAO analysis of Medicare Part B claims data for 2005.

Notes: Dollar amounts may not sum to totals due to rounding. To calculate the number of ultrasound exams, we counted the exams themselves that were paid under Part B, as well as ultrasound procedures classified solely as physician services that do not include a separately billed exam. Ultrasound exams were defined as HCPCS codes in the BETOS categories for echography in addition to 10 diagnostic ultrasound codes that were not in these categories. Calculations are based on the assumption that mobile ultrasound providers would receive a single transportation fee per beneficiary day. When indicated, mobile ultrasound providers also receive a single equipment set-up payment for each ultrasound exam. Transportation and set-up payment amounts are estimated based on the amount Medicare carriers paid for portable X-ray equipment transportation in the locality where the exam was conducted. See appendix I for more information on how we defined ultrasound exams.

^aIndicates the number of days on which ultrasound exams occurred. For example, if a given beneficiary received at least one ultrasound exam on 2 days, this would count as 2 beneficiary days.

^bBased on exams conducted in either a SNF or nursing facility during a noncovered SNF stay.

Appendix III: Detailed Estimates of the Financial Impact of Changing Medicare Ultrasound Payment Methods

Table 8: Percentage Change in Number of Ultrasound Exams in SNFs, 1995 to 1997			
	Number of ultrasound	d exams	
	1995	1997	Percentage change

States where Medicare provided separate payments for ultrasound			
equipment transportation in 1995 ^a	8,365	28,170	237
States where Medicare did not provide separate payments for			
ultrasound equipment transportation in 1995°	23,281	37,708	62

Source: GAO analysis of Medicare Part B claims data for 1995 and 1997 from the Part B Extract Summary System.

Note: Ultrasound exams that were conducted in a SNF or nursing facility were defined as HCPCS codes in the BETOS categories for echography.

^aBeginning in 1996, there were not any states with carriers that provided separate payments for ultrasound equipment transportation, but carriers in the following states did so in 1995: Arizona, California (Northern), Connecticut, Delaware, Georgia, Iowa, Maine, Maryland, Massachusetts, Missouri, Nevada, New Hampshire, New Jersey, Pennsylvania, and Vermont. We excluded California from our analysis because the policy on payments for ultrasound equipment transportation and set up was not consistent throughout the state.

Appendix IV: Studies on Accreditation of Facilities and the Credentialing of Sonographers

Author/title	Objective(s) of study	Study methods	Study results
David G. Stanley, "The Importance of Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL) Certification for Noninvasive Peripheral Vascular Tests: The Tennessee Experience," <i>The Journal for Vascular Ultrasound</i> , vol. 28, no. 2 (2004).	To determine the accuracy of noninvasive vascular ultrasound procedures conducted by accredited and nonaccredited facilities.	The study compared the results of noninvasive vascular ultrasound procedures performed by an accredited facility to the results of studies that were initially performed by both accredited and nonaccredited facilities. The study reviewed a total of 437 ultrasound carotid duplex exams. ^a	
Alfred Z. Abuhamad et al., "The Accreditation of Ultrasound Practices Impact on Compliance with Minimum Performance Guidelines," <i>Journal of Ultrasound in Medicine</i> , vol. 23, no. 8 (2004).	To determine the effectiveness of the American Institute of Ultrasound in Medicine (AIUM) accreditation program in improving compliance with standards and guidelines for the performance of obstetric and gynecologic ultrasound examinations. ^b	The scores of case studies in 82 AIUM accreditation applications were compared with their respective scores at the time of reaccreditation 3 years later. To account for the element of time, scores of applications that recently completed first-time accreditation were also compared as a control group.	The study found that practices that applied for, and were granted, ultrasound accreditation were able to improve the scores of case studies and to achieve compliance with AIUM minimum standards and guidelines for the performance of gynecologic and obstetric ultrasound examinations. The study concluded that the improvement in scores should translate into an enhancement of the quality of the ultrasound practice.
O. William Brown, et al., "Reliability of Extracranial Carotid Artery Duplex Ultrasound Scanning: Value of Vascular Laboratory Accreditation," Journal of Vascular Surgery, vol. 39, no. 2 (2004).	To evaluate the reliability of carotid duplex ultrasound scanning procedures performed by nonaccredited vascular laboratories and to assess the clinical effect on patient management. ^a	The study compared the quality and reliability of carotid duplex ultrasound scanning procedures performed by a nonaccredited vascular laboratory with repeat examinations performed in the Beaumont laboratory, which is accredited by the Intersocietal Commission for Accreditation of Vascular Laboratories.	The study found that of the 174 patients referred for surgical evaluation for carotid endarterectomy, 88 of these patients did not have the severe or critical carotid stenosis (narrowing) that had been diagnosed initially. Since these patients had all been referred for carotid endarterectomy, unnecessary and potentially dangerous operations were avoided when the accredited laboratory disproved the false positive results from the nonaccredited facilities. For an additional 19 patients, the disease severity had been significantly underestimated by the nonaccredited laboratories.

Appendix IV: Studies on Accreditation of Facilities and the Credentialing of Sonographers

Author/title	Objective(s) of study	Study methods	Study results
S. Boswell et al., "Practice Patterns and Membership Opinion About the Value of Credentialing and	Patterns and Membership vascular technologists and members of the Society of Diagnostic Medical Sonograph perform vascular procedures and the Society for Vascular		The study found that 12 percent of (4,782) carotid duplex procedures considered in the study were repeated annually.
Accreditation: Results of a Membership Survey," <i>Journal of Diagnostic Medical Sonography</i> , vol. 19, no. 6 (2003).	about the value of credentialing undership Survey," Journal gnostic Medical graphy, vol. 19, no. 6 about the value of credentialing and accreditation and to assess their current practice patterns for the performance of carotid duplex ultrasound.	Among the reasons cited by respondents for repeat tests was that the sonographers conducting the exams were not sufficiently competent.	
procedures.		Respondents noted that the original procedures often showed a lack of basic sonography knowledge, resulting in poor quality images.	

Source: GAO based on sources cited above.

^aA duplex ultrasound scan is a noninvasive diagnostic ultrasound procedure that uses color Doppler technology to provide information about blood flow and the condition of the arteries and veins. This test is typically used to diagnose suspected artery disease and other vascular problems, including blockage in the carotid artery in the neck.

^bThe AIUM provides accreditation for practices rather than individuals. As one step in the process, practices applying for accreditation must submit four case studies for each specified area of accreditation (obstetrics, gynecology, breast, and abdomen). These case studies are scored by independent reviewers according to established criteria that conform to the minimum standards and guidelines for ultrasound practices as developed by the AIUM.

^cEndarterectomy is the general term for the surgical removal of plaque from an artery that has become narrowed or blocked. To perform an endarterectomy, the physician makes an incision in the affected artery and removes the plaque contained in the artery's inner lining. This procedure opens the artery and restores blood flow. Physicians use endarterectomy to treat many arteries; however, the most common use is for carotid arteries, which are in the neck and deliver blood to the brain.

Appendix V: Information about Groups That Support Ultrasound Credentialing and Accreditation Requirements

Group	Information on group
The American College of Radiology	The American College of Radiology is a nonprofit, professional association that represents 30,000 diagnostic radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists. The organization's ultrasound accreditation program was established in 1995, and it includes general ultrasound, obstetrics, gynecological, and vascular ultrasound. This accreditation program requires that all sonographers be certified.
The American Society of Echocardiography	The American Society of Echocardiography is a professional organization of physicians, cardiac sonographers, nurses, and scientists involved in echocardiography, which is the use of ultrasound to image the heart and cardiovascular system. The organization was founded in 1975 and has more than 10,000 members nationally and internationally.
American Institute of Ultrasound in Medicine	The American Institute of Ultrasound in Medicine is a multidisciplinary organization that was officially established in 1952. The organization supports professional and public education, research, development of guidelines, and accreditation. The organization's ultrasound practice accreditation council has developed standards for the accreditation of ultrasound practices.
American Registry for Diagnostic Medical Sonography	The American Registry for Diagnostic Medical Sonography is an independent nonprofit organization that, for 29 years, has awarded credentials to ultrasound professionals through examinations. The organization offers certification in three ultrasound clinical specialties: Registered Diagnostic Medical Sonographer, Registered Diagnostic Cardiac Sonographer, and Registered Vascular Technologist. The organization has over 44,000 actively certified ultrasound professionals.
Cardiovascular Credentialing International	Cardiovascular Credentialing International is an independent nonprofit organization that awards credentials to vascular technology professionals through credentialing examinations. The organization administers credentials in four cardiovascular technology specialties: Certified Cardiographic Technician, Registered Cardiovascular Invasive Specialist, Registered Cardiac Sonographer, and Registered Vascular Specialist.
Intersocietal Commission for the Accreditation of Echocardiography Laboratories	The Intersocietal Commission for the Accreditation of Echocardiography Laboratories has been in operation since 1996 and currently has accredited over 900 echocardiography laboratories in the United States and Canada. The commission provides a laboratory peer-review evaluation program for echocardiography procedures.
Intersocietal Commission for the Accreditation of Vascular Laboratories	The Intersocietal Commission for the Accreditation of Vascular Laboratories has been in operation since 1991 and currently has over 1,400 accredited laboratories in the United States and Canada. The organization provides a peer-review process of laboratory accreditation for noninvasive vascular diagnostic testing.
Joint Review Committee on Education in Diagnostic Medical Sonography	Founded in 1979, the Joint Review Committee on Education in Diagnostic Medical Sonography is the only nationally recognized organization that accredits diagnostic medical sonography programs. The primary purpose of the organization is to establish, maintain, and promote appropriate standards of quality for educational programs in diagnostic medical sonography and to provide recognition for educational programs that meet or exceed these standards.
Society of Diagnostic Medical Sonography	The Society of Diagnostic Medical Sonography is a professional membership organization founded in 1970 to promote, advance, and educate its members and the medical community in the science of diagnostic medical sonography. The organization has over 17,000 members and is the largest association of sonographers and sonography students in the world.

Appendix V: Information about Groups That Support Ultrasound Credentialing and Accreditation Requirements

Group	Information on group
Society for Vascular Surgery	The Society for Vascular Surgery is the oldest and largest national association of vascular surgeons in the United States. It was founded in 1947 and merged with the American Association for Vascular Surgery in 2003. The Society has a membership of more than 2,200 vascular surgeons. Society members serve on the boards of major vascular sonographer associations as well as the major ultrasound credentialing and accrediting organizations.
Society for Vascular Ultrasound	The Society for Vascular Ultrasound is the only national professional organization dedicated exclusively to the advancement of noninvasive vascular technology used for diagnostic purposes. The organization's membership is comprised of more than 4,100 registered vascular technologists, sonographers, nurses, and physicians.

Sources: GAO interviews and analysis of information presented in the letter from the Coalition for Quality in Ultrasound to MedPAC, September 3, 2004, and groups' Web sites concerning their history, mission, and membership, including *Who's Who in Sonography, Membership Associations*, http://www.sdms.org/about/who.asp, downloaded October 23, 2006.

Appendix VI: Comments from the Centers for Medicare & Medicaid Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

200 Independence Avenue SW Washington, DC 20201

DATE:

JUN 1 5 2007

TO:

A. Bruce Steinwald

Director, Health Care Government Accountability Office

FROM:

Leslie V. Norwalk, Esq.

Acting Administrator

SUBJECT: GAO Draft Report: "MEDICARE ULTRASOUND PROCEDURES:

Consideration of Payment Reforms and Technician Qualification

Requirements" (GAO-07-734)

Thank you for the opportunity to review and comment on the General Accounting Office's (GAO) draft report "Medicare Ultrasound Procedures: Consideration of Payment Reforms and Technical Qualification Requirements" (GAO-07-734). We appreciate the GAO's efforts to ensure that the Centers for Medicare & Medicaid Services' (CMS) coverage, quality, and payment services encourage providers to deliver the best possible care to Medicare beneficiaries, particularly those receiving ultrasound diagnostic services from sonographers.

The CMS is committed to ensuring that its beneficiaries receive high quality care and maintains several clinical quality programs to carry out this commitment. The GAO's report particularly speaks to the national coverage program, under which CMS develops national coverage determinations (NCDs) under section 1862(a)(1) of the Social Security Act (the Act), and the Conditions of Participation (CoP) process, under which CMS promulgates regulations under the Act for institutional and non-institutional providers to meet as a condition of participating in the Medicare program. CMS also encourages States to use their own authorities to ensure that highly trained, capable professionals deliver services throughout their own jurisdictions. It is for this reason that CMS offers an alternative to GAO's recommended approach for ensuring sonographer quality (see "CMS Response" below).

GAO Recommendation:

The GAO recommends that CMS require Medicare-participating sonographers to be credentialed and/or work in an accredited facility. Furthermore, the GAO advises CMS to weigh the advantages and disadvantages of implementing an NCD compared with promulgating regulations that this requirement be a condition for Medicare payment.

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CMS Response:

Provider Quality Issues

The CMS supports the GAO's interest in the quality of ultrasound services; however, the Agency asserts that CMS' authorities under the Act are not the most effective mechanism for addressing sonographer quality. Rather, we recommend that States engage their own licensing bodies in implementing sonographer licensure programs that address the competency/qualification issues GAO addresses in the report.

In the report, the GAO offers two potential avenues for CMS to use its administrative authorities under the Social Security Act—(1) by issuing an NCD; or (2) by promulgating a CoP regulation. While both authorities are integral cornerstones of CMS' clinical quality assurance program, neither of these administrative approaches are appropriate mechanisms for CMS to promulgate sonographer credentialing requirements in order to deliver ultrasound procedures.

We note the regional variation in carrier coverage policies regarding the provision of ultrasound services; however, we believe that a national policy would not take into account regional variations in access to care, state licensing requirements, etc. To remain sensitive to the needs of local communities in providing ultrasound services, CMS recommends that States and local carriers continue to review sonographer qualification requirements on a state-by-state level.

We note that the report indicates that in 2005, of the 28 million ultrasound exams furnished to beneficiaries under Part B, 68 percent were furnished in physicians' offices, and 31 percent in hospital outpatient departments. The statute does not provide for conditions of participation for physicians.

Conditions of participation do apply to hospitals. The current Medicare hospital CoPs address indirectly the specific competencies or qualifications standards for technicians providing ultrasound services. For example, if a hospital provides ultrasound services the hospital is responsible for ensuring the quality and the safety of the care provided as per the existing requirements.

In the hospital setting, most ultrasound services are provided in or supervised by the imaging or radiological department. Specifically, the requirements at 42 CFR 482.26, "Radiologic Services" state, "The hospital must maintain, or have available, diagnostic radiological services. If therapeutic services are also provided, they as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications."

Additionally, as required at 42 CFR 482.11, "Compliance with Federal, State and Local Laws," those personnel must meet the specific State licensure requirements relative to their areas of expertise. When a hospital is surveyed for compliance with the Medicare requirements and ultrasound is offered at that facility, it is likely that technician personnel

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files would be reviewed to ensure they have the necessary training and certifications as appropriate for that particular State.

The requirements at 42 CFR 482.21, "Quality Assessment and Performance Improvement" (QAPI) states, "The hospital must develop, implement and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program." Involvement of all hospital departments and the quality indicators they are tracking are determined when surveying for compliance with the Medicare requirements. A hospital radiological department has the opportunity to include indicators related to ultrasound services, such as the quality of the results in the hospital's overall QAPI program.

Approximately 80 percent of the Medicare-participating hospitals are accredited by the Joint Commission. As a Medicare accrediting body, they are required by statute to have standards that meet or exceed the Medicare requirements. The Joint Commission Standard HR.1.20 requires that staff qualifications are consistent with his or her job responsibilities. Additionally, the Joint Commission standards require ongoing maintenance of licensure, certification, or registration as required by law or regulation.

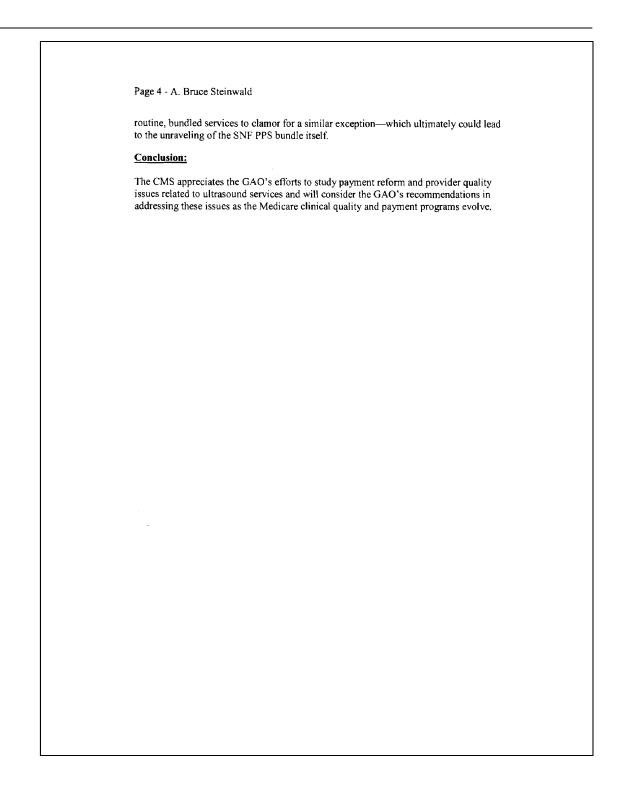
Payment Reform Issues

The CMS concurs with GAO's conclusion (on page 36 of the draft) that "... paying separately under Part B for ultrasound exams and associated equipment and ambulance transportation during Part A-covered SNF stays would undermine the financial incentive of the PPS for SNFs to deliver these services efficiently." Further, we believe that such an action would be contrary to the overall purpose of the skilled nursing facility (SNF) consolidated billing (or "bundling") provision, as discussed in the SNF prospective payment system (PPS) final rule for FY 2001 (65 FR 46791, July 31, 2000):

We do not view the identification of new service categories for exclusion from this provision in terms of a process of continual expansion to encompass an ever-broadening array of excluded services.

As we noted in the May 12, 1998 interim final rule (63 FR 26297), the fundamental purpose of the consolidated billing provision is "...to make the SNF itself responsible for billing Medicare for essentially all of its residents' services, other than those identified in a small number of narrow and specifically delimited exclusions."

Historically, the number of exclusions from the SNF PPS has been relatively small, and has tended to focus on those types of exceptionally intensive, "high cost, low probability" services that clearly lie beyond the normal scope of SNF care. By contrast, an ultrasound exam is a type of routine diagnostic procedure that would fall well within the normal scope of SNF care. Accordingly, we believe that if such a procedure were to be unbundled, it would set a dangerous precedent that would prompt suppliers of many other



Appendix VII: GAO Contact and Staff Acknowledgments

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Acknowledgments	In addition to the contact named above, Sheila K. Avruch, Assistant Director; Jennie Apter; William Black; Kevin Dietz; Sandra Gove; and Carmen Rivera-Lowitt made key contributions to this report.

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