

from the home health PPS payment update published annually each November in the **Federal Register** (Baltimore, MD =0.9907) multiplied by the labor portion of the RNHCI nurse visit from Step 3 (\$ 27.49) =(\$27.23).

**Step 5.** To calculate the non-labor portion of the Standardized Budget Neutral Per-Visit Payment Amount for 1 RNHCI nurse visit, multiply the non-labor portion of 0.23225 by the RNHCI nurse visit rate from Step 2 (\$ 35.81) =(\$ 8.32).

**Step 6.** To calculate the LUPA rate for 1 RNHCI nurse visit, add the products from Step 4 (\$27.49) and Step 5 (\$ 8.32) =(\$ 35.55).

**Step 7.** To calculate the LUPA payment for RNHCI nurse visits to one beneficiary in a 30-day period, multiple the product of Step 6 (\$ 35.55) by the number of visits (12) =(\$ 426.60).

#### BILLING CODE 4120-01-C

#### IV. Other Issues

##### A. Provisions Related to Therapy Services

##### 1. Outpatient Therapy Services Performed "Incident To" Physicians' Services

Section 1862(a)(20) of the Act permits payment for therapy services furnished incident to a physician's professional services only if the practitioner meets the standards and conditions that would apply to the therapy services if they were furnished by a therapist, with the exception of any licensing requirement. We proposed to amend the regulations at § 410.26, § 410.59, § 410.60, and § 410.62 to reflect the statutory prohibition on payment for "therapy" services of individuals who do not meet the existing qualification and training standards for therapists (with the exception of licensure) as these standards are set out in § 484.4.

As discussed in the August 5, 2004 proposed rule, section 1862(a)(20) of the Act refers only to PT, OT, and SLP services and not to any other type of therapy or service. This section applies to covered services of the type described in sections 1861(p), 1861(g) and 1861(l) of the Act; it does not, for example, apply to therapy provided by qualified clinical psychologists. This section also does not apply to services that are not covered either as therapy or as E/M services provided incident to a physician or NPP, such as recreational therapy, relaxation therapy, athletic training, exercise physiology, kinesiology, or massage therapy services.

In the following discussion, the phrase "therapy services" means only PT, OT, and SLP. Also, "therapist" means only a physical therapist,

occupational therapist, and speech-language pathologist.

Section 1861(s)(2)(K) of the Act permits certain NPPs, specifically PAs, NPs, and CNSs, to function as physicians for the purposes of furnishing therapy services which they are legally authorized to perform by the State in which the services are performed. Therefore, in our responses to comments in the following discussion, the statements concerning therapy services that apply to physicians also apply to PAs, NPs, and CNSs.

We received many comments on this proposal from professionals and associations for audiologists, speech-language pathologists, physical therapists, occupational therapists, long term care facilities, kinesiotherapists, massage therapists, athletic trainers, nurses, and physicians such as physiatrists, neurologists, podiatrists, chiropractors, osteopaths, medical groups, and family practitioners.

The proposal describes covered Medicare services and is not intended to affect the policies of other insurers who may cover services that Medicare does not, for example, therapy services performed by massage therapists or athletic trainers.

*Comment:* Several associations believe that this proposal is based on an incorrect interpretation of the intent of section 1862(a)(20) of the Act. Some claim that the proposed clarification is prohibited by the statute. They note the lack of any elaboration upon the Congress' intent in the Conference Report accompanying section 4541(b) of the BBA, but suggest the provision was based on a 1994 OIG report, "Physical Therapy in Physicians' Offices" (OEI-02-90-00590, March 1994). In the view of some commenters, the intended effect of section 1862(a)(20) of the Act was to

apply to incident to therapy services the standards and conditions related to treatment plans, the need for goals, and the requirement that therapy is to be restorative. This position is based on the fact that these standards were the focus of the 1994 OIG report. The commenters point out that the report did not compare therapist services to services furnished by nontherapists in a physician's office, but it only compared the services billed by therapists to those billed by physicians.

Commenters argued that the plain meaning of section 1862(a)(20) of the Act indicates that incident to services are not necessarily furnished by therapists. They point to the parenthetical exclusion of licensure requirements in the statutory language as evidence that the Congress did not intend to apply the personnel requirements applicable to therapists in private practice to incident to therapy services. Some commenters believe this exclusion was intended to preserve the right of physicians to supervise auxiliary personnel that were not licensed as therapists. They suggest that we are creating a de facto licensure requirement.

Comments from the two members of the Congress who introduced the act that resulted in section 1862(a)(20) of the Act support the proposed rule, stating that the proposed clarification meets the intent of the law when it was passed by the Congress in 1997. These commenters confirm that the legislation was based in part on the 1994 OIG report and the intent was to establish "a consistent standard for the delivery for PT services to ensure quality patient care." Two additional comments were received from the Congress in support of the proposal.

*Response:* Our interpretation is based on the plain language of the law: no payment may be made for incident to therapy services “that do not meet the standards and conditions (other than any licensing requirement specified by the Secretary) under the second sentence of section 1861(p) \* \* \*”

The second sentence of section 1861(p) of the Act reads as follows:

“The term ‘outpatient physical therapy services’ also includes PT services furnished an individual by a physical therapist (in his office or in such individual’s home) who meets licensing and other standards prescribed by the Secretary in regulations, otherwise than under an arrangement with and under the supervision of a provider of services, clinic, rehabilitation agency, or public health agency, if the furnishing of such services meets such conditions relating to health and safety as the Secretary may find necessary.”

It is evident then, that the standards and conditions referenced in section 1862(a)(20) of the Act encompass qualifications of the individual providing the therapy. Consequently, we disagree with those commenters who suggest that it was not the intent of section 1862(a)(20) of the Act to apply the personnel qualifications of the second sentence of section 1861(p) of the Act to therapy provided incident to a physician’s service. We believe our interpretation of the law is further supported by the comment received from the Congress members who sponsored the original bill that became section 1862(a)(20) of the Act.

According to the proposed requirements, a person who is trained in therapy, but has not completed the further requirements of therapy licensure, may provide services incident to a physician’s services. These individuals are not therapists, since they are not licensed, but they are qualified personnel who may, under direct supervision, provide therapy services incident to a physician.

A physician may utilize supervised unlicensed staff and may bill for a covered therapy service incident to the physician’s service if it is provided according to Medicare policies, including coverage and incident to policies.

*Comment:* Commenters also note that qualifications at § 484.4 are in the home health agency section of the regulations, while the second sentence of section 1861(p) of the Act (referenced by section 1862(a)(20) of the Act) does not apply to therapy provided in home health agencies.

*Response:* The statute specifies therapy services provided incident to a physician must meet the standards and

conditions that would apply to a therapist, except licensure. For the history of the qualifications for the private practice setting, please see the discussion in this rule as described below in section IV.A.2, “Qualification Standards and Supervision Requirements in Therapy Private Practice Settings.” We proposed to apply to all settings the qualifications in § 484.4 because they are standards that currently apply to therapists in provider settings. It is our intent to make therapist qualifications consistent in all settings (unless otherwise required by statute). Therefore, unless a person meets the standards in § 484.4, except licensure, their services may not be billed as therapy services incident to a physician’s service, regardless of any other training, other licensure or certification or other experience they may have. For example, the services of chiropractors or athletic trainers who do not meet the requirements in § 484.4 except licensure, cannot be billed as therapy services incident to a physician’s service.

*Comment:* Several associations indicated that we are changing our interpretation of the statute. They assumed any instruction relevant to the law was made in 1998 through Transmittal 1606. That transmittal provided guidance for therapy services, but did not address the qualification of the people who furnish therapy incident to physician services. It was also suggested that we delay implementation to allow further study and comment from interested parties. The AMA urged us to withdraw proposed changes and reissue a later proposal after consulting with all affected physician and other health professional organizations.

Also, the commenters note that the Administrative Procedure Act (APA) requires that we characterize this as a change rather than a clarification.

*Response:* In the past, we did not discuss the plain language of the law because we did not believe it needed extensive clarification. However, it has become clear to us that contractors have varied in their policies.

Some contractors created local policies that paid only for services provided by licensed therapists in all settings including incident to a physician’s service. Others had no policies that assured the qualifications of personnel furnishing services billed as therapy services incident to a physician.

Study of the utilization of therapy services, internal discussions with contractors and medical review of claims for the purpose of error rate analysis all suggested that the services

being performed in the offices of physicians did not consistently meet the standards and conditions we applied to therapy services in private practice or in provider settings. Problems associated with an imprecise definition of therapy services were discussed at length in Section 4.1 of the “Study and Report on Outpatient Therapy Utilization” (the DynCorp utilization study) found at <http://www.cms.hhs.gov/medlearn/therapy>. Review of medical records following this report reinforced the personnel qualification problem.

In Pub. 100–04, the Medicare Claims Processing Manual at chapter 5, section 20, there is a list of codes that represent services that are always therapy services (available online at [http://www.cms.hhs.gov/manuals/104\\_claims/clm104c05.pdf](http://www.cms.hhs.gov/manuals/104_claims/clm104c05.pdf)). Whenever these codes are billed, they must have a modifier that identifies the type of therapy (PT, OT, or SLP) and the services provided must meet the standards and conditions that apply to outpatient therapy services. In the medical review of therapy claims, there were frequent observations of “always therapy” services performed by persons other than therapists, which were billed inappropriately as therapy.

Since the qualifications of therapists and therapy services continued to be problematic, we chose to raise the subject of therapist qualifications last year. Last year’s comments made it clear that there is widespread use of nontherapists, particularly athletic trainers, in the offices of physicians and those services are being billed as therapy services. The volume of similar comments this year made it evident to us that the clarification was needed.

We characterize this statement as a clarification because it merely restates the law. Moreover, we announced our clarification in the proposed rule, and it has been subject to comment in last year’s proposed rule and again this year. So, assuming that it did change policy, its promulgation meets the requirements of the APA.

In addition, we note that we continue to pay only for covered services whether they are therapy or other services. Coverage rules in the Program Integrity Manual, chapter 13.5.1, require, for example, that the service be safe, effective, in accordance with accepted standards of medical practice, and furnished by qualified personnel.

We recognize there has been inconsistent application of this statutory requirement. Therefore, in order to allow sufficient time for physicians to adjust their practices, and to avoid disrupting ongoing therapy in affected practices, we will delay implementation

until manual instructions are published. We anticipate publication of manual instructions on or after March 1, 2005.

*Comment:* Many commenters offered the opinion that restricting payment for therapy services to those performed by therapists would reduce access and quality of care and increase costs. They noted that it is more convenient for therapy to be available in a physician's office than at another site. Also, there was concern that therapists may not work in rural areas, especially because there is a shortage of qualified therapists.

*Response:* The statute requires that those who provide therapy services meet therapy standards. It provides an exception for licensure in an incident to setting, but it does not provide an exception for rural areas. Since recent changes allow physical and occupational therapists that are enrolled in Medicare to work for physicians, there is no legal impediment to physicians being able to provide therapy services in their offices without the use of nontherapists. The Department of Labor Bulletin 2572, titled "Occupational Projections and Training Data 2004–05 Edition", suggests no shortage of therapists.

Nor do we find evidence to suggest the quality of care will be decreased by the use of personnel trained in therapy services as opposed to those trained in other disciplines. The cost of therapy services to Medicare will not be changed by the use of appropriately trained personnel.

*Comment:* Many comments from physical therapists and PT associations agreed in principle with consistently defining the qualifications for therapists in all settings. They point out that, although the statute allows unlicensed people to provide therapy services incident to the services of a physician, the purpose of licensure is to assure that services are safely and effectively furnished by professionals who have demonstrated the necessary knowledge and skills. The statute permits the use of therapists who have not met licensing requirements and those whose licenses were revoked due to malpractice or fraud. The supervision requirement that the physician be present somewhere in the suite, but not in line of sight, is insufficient to assure the safety and quality of service provided by unlicensed staff.

*Response:* Although the law permits unlicensed individuals to provide services incident to the services of a physician, we believe physicians will be motivated to screen employees to weed out sanctioned or incompetent people who have training in therapy since

physicians would be liable for the actions of an incompetent employee. We require direct supervision of the employee by the physician as a minimum standard, but a physician will provide whatever guidance and supervision is required to assure the safety, effectiveness and quality of the service.

*Comment:* Many comments were received from individuals such as athletic trainers, kinesiologists, massage therapists and chiropractors describing their training as equal or superior to therapists' and suggesting that they provide care similar to therapists.

*Response:* The statute allows Medicare to pay only for PT, OT and SLP services. Comments from therapists and nontherapists agreed that their training and licensure is unique to their professions, and they are separately trained and licensed for those unique professions. It is clear that many nontherapist health care practitioners are well-trained professionals dedicated to the provision of quality treatment for their patients. However, their training is not in PT, OT, or SLP, but in the other disciplines for which they are licensed or accredited.

*Comment:* A number of physicians and associations for physicians wrote to tell us that they believe it is their right and within their authority to decide who can provide effective therapy services in their offices.

*Response:* The statute requires Medicare to pay only for services that meet the standards and conditions, except licensure, that apply to therapists. It is the right and responsibility of a physician to recommend services for patients that in the physician's judgment are needed and effective. Medicare, however, need not pay for all services that a physician recommends. We are required to pay for services that are covered in the statute and to deny payment for services that are not covered, even if the physician considers those services necessary and effective.

*Comment:* Some physicians wrote to tell us they are currently billing Medicare for therapy services when athletic trainers perform services in their offices. Several commenters asked what services may be billed to Medicare when provided by auxiliary staff who are qualified as athletic trainers, or who have certification in fields other than therapy.

*Response:* While some carriers may have paid claims for incident to therapy services furnished by individuals without therapy training, we have never had a policy that permits athletic

trainers or any other staff who do not have training in PT to provide services that are billed as PT services. Carrier payment for a service is not conclusive evidence that the service was appropriately rendered. Billing with a code that does not accurately represent the service provided is inappropriate. If identified by carrier medical review, these claims must be denied, and further development of the claim may be indicated to determine if there was intent to bill improperly.

Medicare defines PT, OT and SLP as services that require the skills of a physical therapist, occupational therapist or speech-language pathologist. Therapy codes are priced based on the salaries and expenses of therapists and we expect that therapy claims are made for services of therapists (or, for incident to services by someone with their training, except for licensure).

When a service is not a covered service, it is inappropriate to bill Medicare for that service as a service incident to a physician, or as an E/M service. For example, if a service is appropriately described as acupuncture or athletic training or massage therapy, Medicare will not pay for that service because it is not covered.

A physician may not bill Medicare for a service that is on the list of "always therapy" services (see Pub. 100–04, the Medicare Benefit Policy Manual, chapter 5, section 20) if the service was done by staff that is not qualified to provide a skilled therapy service, because that is not a covered therapy service. The "always therapy" codes always require a modifier to describe whether the service was PT, OT or SLP.

There are covered services that other staff, such as athletic trainers, may perform with other training, however, these are not therapy services. Other codes on the therapy list are "sometimes therapy" services and require modifiers only when they are therapy services rather than physician services. For example, a physician may apply a surface neurostimulator (CPT 64550) as an isolated service, outside of a therapy plan of care and appropriately bill the code without a therapy modifier. That service is not a therapy service. If that physician supervises auxiliary personnel in the provision of that same nontherapy service, the auxiliary personnel does not have to be qualified as a therapist because the service rendered is not therapy. In any case, when Medicare is billed for a service, the person providing the service must be qualified to provide the service, as determined by the contractor in accordance with coverage requirements

in Pub. 100-08, the Medicare Program Integrity Manual, chapter 13.5.1. However, if a therapist provides the service under any circumstance, or if either the physician or qualified personnel provides the service as part of a therapy plan of care, it is a therapy service and it requires a modifier. In cases where there is doubt, the contractor will determine whether the service is therapy or is not therapy.

Further information about services that may be completed by non-therapists will be available in implementing instructions.

*Comment:* The American Chiropractic Association commented that doctors of chiropractic are authorized to perform PT services in all but two States, Michigan and Washington. They request that we note that fact in our commentary and in the regulation. They note that Doctors of Chiropractic are included in the definition of "physician" and they propose language in addition to that in § 484.4 to define the qualifications of chiropractors, in order to recognize the State-authorized practice privileges of Doctors of Chiropractic.

*Response:* Chiropractors may bill services to Medicare as physicians, but only for the purposes of providing manipulation of the spine for the correction of a subluxation, which is a chiropractor service, and not a therapy service. For these manipulation services, chiropractors may directly supervise employees who provide incident to services. However, as Medicare physicians, chiropractors are not authorized to order therapy services or to perform any other services. To qualify to provide therapy services incident to a physician, chiropractors must meet all of the criteria set forth at § 484.4 except licensure.

*Comment:* Several associations and some individuals commented that we are creating a monopoly for therapists to provide therapy services and unnecessarily restricting other professions from providing therapy services.

*Response:* We are bound by the statutory authority given to us in section 1832 of the Act to pay only for services for which there are benefits enumerated in the statute. PT, OT and SLP have benefits in section 1861 of the Act. Therefore, Medicare pays only for those services.

*Comment:* Several commenters noted that some NPPs, specifically PAs, NPs, and CNSs, may perform therapy services billable under Medicare as therapy services if their State scope of practice allows. The commenters question whether those NPPs may also perform

therapy services incident to a physician or NPP.

*Response:* Medicare does not impose therapy training requirements on physicians whose State scope of practice allows them to perform therapy services. Section 1861(s)(2)(K) of the Act permits PAs, NPs, and CNSs, to furnish services which would be physicians' services, that is, to function as physicians for purposes of furnishing services, including therapy services, which they are legally authorized to perform by the State in which the services are performed. Therefore, this final rule has been modified to reflect that in States that authorize physicians, PAs, NPs, and CNSs to provide one or more of the therapy services (PT, OT, or SLP services), those NPPs may provide the services incident to the services of a physician or NPP under the same conditions as physicians, that is, without meeting the training requirements applicable to therapists.

#### *Results of Evaluation of Comments*

To the extent that this policy is different from current manual text, we proposed this rule and received comments. We are finalizing the proposal in this final rule with the changes noted above in accordance with the APA. We will implement this regulation through manual guidance on or after March 1, 2005.

#### 2. Qualification Standards and Supervision Requirements in Therapy Private Practice Settings

Sections 1861(g) and (p) of the Act include services furnished to individuals by physical and occupational therapists meeting licensing and other standards prescribed by the Secretary if the services meet the necessary conditions for health and safety. These services include those furnished in the therapist's office or the individual's home. By regulation, we have defined therapists under this provision as physical or occupational therapists in private practice (PTPPs and OTPPs).

Under Medicare Part B, outpatient therapy services, including physical and occupational therapy services, are generally covered when reasonable and necessary and when provided by physical and occupational therapists meeting the qualifications set forth at § 484.4. Services provided by qualified therapy assistants, including physical therapist assistants (PTAs) and occupational therapy assistants (OTAs), may also be covered by Medicare when furnished under the level of supervision by the therapist that is required for the setting in which the services are

provided (institutions and private practice therapist offices). For PTPPs and OTPPs, the regulations now specify only that the PT or OT meet State licensure or certification standards; the regulations and do not currently refer to the professional qualification requirements at § 484.4.

Since 1999, when therapy services are provided by PTAs and OTAs in the private practice of a PT or OT, the services must be personally supervised by the PTPP or OTTPP. In response to a requirement to report to the Congress on State standards for supervision of PTAs, we contracted with the Urban Institute. The Urban Institute found that no State has the strict, full-time personal supervision requirement, for any setting, that Medicare places on PTAs in PTPPs. (The report examined only PTAs, who are more heavily regulated by the States than OTAs).

To provide a consistent therapy assistant supervision policy, we proposed to revise the regulations at § 410.59 and § 410.60 to require direct supervision of PTAs and OTAs when PTs or OTs provide therapy services in private practice. We also specifically solicited comments regarding the proposed PTA supervision policy, and whether or not it would have implications for the quality of services provided, or for Medicare spending, either through increased capacity to provide these services, or, in the event that the Congress again extends the moratorium on the implementation of the limits on Medicare reimbursement for therapy services imposed by the BBA of 1997.

In addition, as discussed in the August 5, 2004 proposed rule, the current OTTPP or PTPP regulations at § 410.59(c) and § 410.60(c) do not reference qualification requirements for therapy assistants or other staff working for PTs and OTs in private practices. In order to create consistent requirements for therapists and for therapy assistants, we proposed to restore the qualifications by adding the cross-reference to the qualifications at § 484.4 for privately practicing therapists and their therapy assistants at § 410.59 and § 410.60.

*Comment:* Commenters representing therapy organizations, as well as individual providers, were supportive of our proposal to revise the regulations at § 410.59 and § 410.60 to require direct, rather than personal, supervision of PTAs and OTAs when therapy services are provided by PTs or OTs in private practice.

(We use the 3 supervision levels defined at § 410.32, personal, direct, and

general, to describe the supervision requirements for various Medicare services and settings.)

Many commenters also stated that this is consistent with the Medicare requirements in other provider settings, such as hospitals, HHAs and rehabilitation agencies and is also consistent with the Medicare requirements for therapists in private practice that were in place prior to 1999. Commenters also believe that this will assist in ensuring access to therapy services and in protecting patient privacy.

*Response:* Requiring direct supervision of therapy assistants in PT and OT private practice settings is consistent with the supervision requirements that PTs and OTs in independent practice were required to meet, prior to 1999, at § 410.59(c) and § 410.60(c). This direct supervision requirement in PT and OT private practices requiring the therapist to be on site or “in the office suite” differs from our therapy assistant supervision requirements in institutional settings (for example, outpatient hospital departments, HHAs, and rehabilitation agencies). In those settings, PTs and OTs may provide general supervision of therapy assistants without being on-site.

We agree that changing the level of supervision of therapy assistants from personal to direct will help to improve access to medically necessary services.

*Comment:* A few commenters stated they believe permitting general supervision, rather than direct, is more consistent with State therapy supervision requirements. While State requirements vary, this variation may be due to the fact that PTAs are not licensed in some States. Other commenters stated that therapy assistants are qualified to provide services without having therapists in-the-room to provide personal supervision.

*Response:* A review of State practice acts revealed that Medicare’s personal in-the-room supervision requirement for therapy assistants in PT and OT private practices was more stringent than any State supervision requirement for any setting. The Urban Institute report also found that most States permit a supervision level similar to our general supervision requirement for institutional settings. However, we believe that services delivered by therapy assistants in private practices require a higher level of therapist supervision than those provided in institutional settings where stringent standards for Medicare participation are enforced through State survey and

certification programs, rather than the simplified carrier enrollment process for the PT or OT private practice offices.

*Comment:* One commenter stated that only licensed therapists should be allowed to provide and bill for therapy and another commenter demanded that therapy services only be reimbursed when provided by a therapist, not any other professional, including nurses, PAs, or chiropractors, and not by therapy assistants. They suggested that without this requirement there would be program abuses.

*Response:* We concur with the therapy associations and the overwhelming majority of commenters that therapy assistants are qualified by their training and education to provide services without the personal in-the-room supervision in the private practice setting. This does not mean, however, that therapy assistants may bill for the services they provide. Under the law, only PTs and OTs in private practice may bill Medicare for the therapy services provided by PTAs and OTAs. These therapists enroll in the Medicare program and receive a provider identification number (PIN) in order to file claims for the therapy services provided as a PTPP or OTTP. Institutional therapy providers bill Medicare on behalf of the PTs, OTs, and speech language pathologists who provide therapy services in these settings.

Other professionals, including nurses, athletic trainers, and chiropractors do not meet the statutory requirements for therapists in section 1861(p) of the Act and as implemented at § 484.4. We proposed to amend the regulations at § 410.59 and § 410.60 to specify that only individuals meeting the qualification standards and training consistent with § 484.4 may bill and receive Medicare payment for therapy services. In addition, a State license or certification in PT or OT will continue to be required for therapist providing services as PTPPs or OTTPPs.

When PAs, NPs, or CNSs are authorized by their State practice acts to provide physical or occupational therapy services, and these NPPs are acting within their capacity to provide physician services under section 1861(s)(2)(K) of the Act, their services are considered therapy services.

*Comment:* One commenter stated that allowing lesser trained individuals such as therapist assistants to provide services if a therapist supervises, but prohibiting physicians from delegating performance of these services to doctors of chiropractic inappropriately gives therapists more authority than physicians.

*Response:* Medicare law recognizes chiropractors as physicians, but only for the limited purpose of providing manipulation of the spine for the correction of a subluxation. In order to qualify as a PT or OT for Medicare purposes, chiropractors would need to meet all of the criteria set forth at § 484.4.

*Comment:* In response to our request for information on the impact of this proposed change on the quality of services and Medicare spending, several individuals stated that the proposed change would not affect the way therapists practice, since they are fully accountable for services provided under their direction and, therefore, the change would not diminish the quality of services. Furthermore, commenters believe the change would also allow the appropriate and efficient utilization of therapist assistants because the in-the-room supervision unnecessarily drives up the cost of health care without providing additional consumer protection.

The American Physical Therapy Association (APTA) anticipates there will be little, if any, increase in spending as a result of this policy and believes that any increases would be due to improving access to medically necessary outpatient therapy services provided by qualified practitioners. For spending implications, the APTA believes it is highly unlikely that physical therapists would significantly alter their staffing patterns and thereby increase spending as a result of this change in policy. The majority of States have laws that establish limits on the number of PTAs that a PT can supervise (referred to as “supervision ratios”). For example, a large number of States have a supervision ratio of one PT to two PTAs. There are also a limited number of PTAs whom PTs could supervise, and APTA does not anticipate substantial growth in the number of PTAs in the foreseeable future. To the contrary, the number of PTA education programs is declining.

Furthermore, services of PTs in private practice comprise a relatively small percentage of services billed under the Medicare program. Therefore, the overall financial impact of any change in the supervision requirement in this setting would be minimal.

*Response:* We appreciate the information provided by the commenters. Other opportunities already exist for therapists to provide services under Medicare in rehabilitation agencies and CORFs where the therapy assistant supervision level is general. Therapists opting to utilize therapy assistants might be more

likely to own a rehabilitation facility where the physical or occupational therapy assistant supervision level is general, rather than a private practice office where the therapist is required to be on-site to supervise services of the therapy assistant. The Urban Institute Report confirmed the limited number of therapy assistants available to be hired and found that workforce and distribution percentages of PTs and PTAs parallel each other, with nearly 25 percent of PTAs employed by PTPPs. We believe that the State supervision requirements and the limited number of PTAs are likely to limit the financial implications of this change. We plan to monitor this area to determine whether volume changes occur and, if so, in what settings they occur.

*Comment:* Commenters supported our proposal to revise § 410.59 and § 410.60 to cross-reference the qualifications at § 484.4 for privately practicing therapists and their therapy assistants.

*Response:* We appreciate the numerous letters of support for this proposal, including the national and State-level therapy organizations, other professional organizations, and many therapists and therapy assistants.

#### *Result of Evaluation of Comments*

We will finalize the proposed revisions to § 410.59 and § 410.60 to require direct supervision of PTAs and OTAs when therapy services are provided by PTs or OTs in private practice and also to cross-reference the qualifications at § 484.4 for privately practicing therapists and their therapy assistants.

### 3. Other Technical Revisions

We proposed technical corrections to § 410.62 to refer consistently to SLP (currently the terms “speech pathology” and “speech-language pathology” are used interchangeably) and proposed revisions to § 410.62(a)(2)(iii) to appropriately reference § 410.61 (the current reference is to § 410.63).

We also proposed removing subpart D, Conditions for Coverage: Outpatient Physical Therapy Services Furnished by Physical Therapists, from part 486. Our November 1998 rule (63 FR 58868) discussed replacing this subpart with a simplified carrier enrollment process for physical or occupational therapists in private practice; however, the conforming regulatory change to remove subpart D was never made.

In addition, we proposed a technical change at § 484.4 to correct the title “physical therapy assistant” to “physical therapist assistant” and proposed amending § 410.59(e) and § 410.60(e) to include a reference to the

2-year moratorium on the therapy caps established by section 624 of the MMA.

*Comment:* Commenters representing therapy specialty organizations supported these changes.

*Response:* We will finalize these changes as proposed.

#### *Result of Evaluation of Comments*

We are finalizing the changes as proposed.

### *B. Low Osmolar Contrast Media*

High osmolar and low osmolar contrast media (LOCM) are used to enhance the images produced by various types of diagnostic radiological procedures. When the Medicare physician fee schedule was established, findings of studies of patients receiving both types of contrast media had been published, and the ACR had adopted criteria for the use of LOCM. At that time, we determined that the older, less expensive high osmolar contrast media (HOCM) could be used safely in a large percentage of the Medicare population. However, we also decided that separate payment for LOCM may be made for patients with certain medical characteristics. We adopted the ACR criteria, with some modification, as the basis for a policy that separate payments are made for the use of LOCM in radiological procedures for patients meeting certain criteria. These criteria were established at § 414.38. Under these conditions, we pay for LOCM, utilizing HCPCS codes A4644 through A4646.

In the August 5, 2004 rule, we proposed to revise the regulations at § 414.38 to eliminate the restrictive criteria for the payment of LOCM. This proposal would make Medicare payment for LOCM consistent across settings since, under the OPFS, there is no longer a payment difference between LOCM and other contrast materials.

We also proposed that, effective January 1, 2005, payment for LOCM would be made on the basis of the ASP plus six percent in accordance with the standard methodology for drug pricing established by the MMA. However, because the technical portions of radiology services are currently valued in the nonphysician work pool and the CPEP inputs for these services are not used in calculating payment, we also indicated we would continue to reduce payment for LOCM by eight percent to avoid any duplicate payment for contrast media.

*Comment:* Commenters representing radiology, interventional radiology, and imaging contrast manufacturers were supportive of this proposed change; however, our payment methodology of

ASP plus six percent minus eight percent was questioned. Two commenters also believe that the implementation date for the application of ASP methodology should be changed from January 1, 2005. One requested an effective date of April 1, 2005 and the other requested an effective date of January 1, 2006.

*Response:* We appreciate the commenters' support for this change. We stated in the proposed rule that effective January 1, 2005, payment for LOCM would be made on the basis of the ASP plus six percent. However, there is an October 30, 2004 deadline for submission of the ASP data used for the January 1, 2005 payment, and this date occurred prior to our finalizing the proposed payment methodology for LOCM. Therefore, the ASP payment methodology for LOCM will be made effective April 1, 2005. Manufacturers of LOCM will be required to submit their fourth quarter 2004 (4Q04) ASP information to us on or before January 30, 2005. Subsequent data must be submitted within 30 days after the end of each calendar quarter. The 4Q04 data will be used to determine the April 1, 2005 ASP plus six percent payment limits. Further information on the specific format of the data submission and the address to which the information can be sent is found on the CMS ASP Web site, specifically at <http://www.cms.hhs.gov/providers/drugs/asp.asp>.

Our policy to reduce payment for LOCM by 8 percent stems from the fact that the technical component RVUs for these procedures took into account the use of (and expenses for) HOCM in the (see the November 25, 1991 final rule (56 FR 59502)). However, since that time, the price differential between HOCM and LOCM has declined. In addition, upon further review, we are not able to determine accurately the degree of duplicate payment that might occur when both the imaging procedure and LOCM are billed. Therefore, we are not applying the eight percent reduction to the LOCM payment as proposed. The payment for LOCM will be consistent with the payment rate for the majority of drugs administered by physicians.

*Comment:* One contrast agent industry association suggested that we issue additional codes for the reporting of contrast media.

*Response:* For 2005, we are continuing to use the current three HCPCS codes in the reporting of low osmolar contrast agents. However, we are exploring the possibility of additional codes to accurately capture the cost differences among all contrast agents as well as the differing clinical