

therapy services, and the related nursing, and social and psychological services. Generally, administrative costs associated with the provision of such services is incorporated into payment amounts established under the PFS through the PE RVUs representing the resources necessary to perform each service in the physician office or nonfacility setting. Therefore, we believe it unnecessary to separately compensate CORFs for CORF physician services given that such services are administrative in nature, and proposed at § 414.1105(b) not to separately pay CORFs for CORF physician services.

To ensure that CORFs are not paid twice for CORF services, we proposed at new § 414.1105 to base payment for a CORF service on the applicable fee schedule amount only to the extent that payment for such service is not included in the payment amount for other CORF services. Accordingly, under proposed § 414.1105(c) a CORF could not bill separately for supplies included in the PE RVU component of the payment amount established for a service under the PFS. However, we noted that CORFs could bill separately for certain splint and cast supplies for the application of casts and strapping because these supplies have been removed from the payment amounts established under the PFS. We also noted that Medicare makes separate payment for surgical dressings, which are also referenced at section 1861(s)(5) of the Act, only when used by the beneficiary in his or her home. No separate payment is made when these surgical dressings are used in the CORF setting; rather the dressings' costs are bundled into the payment amount established under the PFS for the provided services.

For CORF services based on the payment amount determined under the PFS, we proposed at new § 414.1105(a)(2) to use the PFS amount applicable to services furnished in a nonfacility setting, with no separate payment made for facility costs. We proposed to use the PFS nonfacility amount for CORF services in order to offset any costs of providing such services in the CORF setting. [Note: in the proposed rule we incorrectly referenced the codification of the regulation text under proposed subpart M as § 414.1001 or § 414.1101 rather than § 414.1105. However, the proposed regulation text was presented accurately as § 414.1105 in the "List of Subjects" under the proposed subpart.]

Other than the objection discussed above in section II.K.7 regarding the proposed removal of the CORF provision for drugs and biologicals, we

did not receive other comments about our proposal to create a regulatory provision to specify the payment methodologies for the CORF services identified at section 1861(cc)(1) of the Act. Therefore, we are finalizing our proposal to add a new regulatory provision defining the payment methodologies used to pay for CORF services except that we also include a section for payment of drugs and biologicals included within the definition of CORF services under the new § 410.100(j), as explained in section II.K.7. We will implement this proposal, including the addition of the payment provision for drugs and biologicals included within the definition of CORF services under the new § 410.100(j), and revise, by adding a new subpart M to part 414. The basis and scope for payment for CORF services is set forth at § 414.1100 and § 414.1105 sets forth the payment methodology for CORF services, including identifying the applicable fee schedule for each type of CORF service identified in § 410.100.

12. Vaccines

Section 485.51(a) defines a CORF as a nonresidential facility that "is established and operated exclusively for the purpose of providing" rehabilitation services by or under the supervision of a physician. Because vaccines administered in the CORF setting are not rehabilitation services furnished under a plan of treatment relating directly to the rehabilitation of the patient (or, presumably, even medically necessary for the rehabilitation of the patient), in accordance with § 485.51(a), a CORF may not administer vaccines to its patients. However, in the CY 2008 PFS proposed rule we noted that nothing in the Medicare statute would prohibit a CORF from providing pneumococcal, influenza, and hepatitis B vaccines to its patients provided the facility is "primarily engaged in providing * * * diagnostic, therapeutic, and restorative services to outpatients for the rehabilitation of injured, disabled, or sick persons" (section 1861(cc)(2)(A) of the Act). Accordingly, under the statute, such vaccines may be covered separately from the CORF services benefit under section 1861(s)(10) of the Act—defining the term "medical and other health services" to include the pneumococcal, influenza, and hepatitis B vaccines—provided the applicable conditions of coverage under § 410.58 and § 410.63 are met. In order to include coverage and payment for these vaccines when provided to CORF patients in the CORF setting, we proposed to amend the CORF conditions of participation at

§ 485.51 to permit CORFs to provide vaccines to their patients in addition to rehabilitation services. Such vaccines would be covered in the CORF setting provided the conditions of coverage under § 410.58 and § 410.63 are met. In accordance with sections 1833(a)(1) and 1842(o)(1) of the Act, payment for covered pneumococcal, influenza, and hepatitis B vaccines provided in the CORF setting is based on 95 percent of the average wholesale price (AWP).

Comment: We received a few comments strongly supporting the proposal to permit vaccines to be provided in the CORF setting in addition to the CORF services. These commenters also strongly supported our proposal to clarify our policy regarding the administration of vaccines to CORF patients by revising the CORF conditions of participation to permit the provision of vaccines, in addition to CORF services. These commenters believe that increasing the number and types of providers where vaccinations can be furnished will not only help to ensure increased access to these vaccinations but will result in improved health outcomes and lower costs.

Response: We agree with the commenters and will implement our proposal to revise the CORF conditions of participation, accordingly.

L. Compendia for Determination of Medically-Accepted Indications for Off-Label Uses of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen (§ 414.930)

1. Background

a. Statutory Requirements

Section 1861(t)(2)(B)(ii)(I) of the Act lists three drug compendia that may be used in determining the medically-accepted indications of drugs and biologicals used in an anti-cancer chemotherapeutic regimen. The three drug compendia listed are:

- American Hospital Formulary Service-Drug Information (AHFS—DI)
- American Medical Association Drug Evaluations (AMA—DE)
- United States Pharmacopoeia Drug Information (USP—DI)

Section 1861(t)(2) of the Act provides the Secretary the authority to revise the list of compendia for determining medically-accepted indications for drugs. Due to changes in the pharmaceutical reference industry, fewer of the statutorily named compendia are available for our reference. (That is, AMA—DE is no longer in publication; USP—DI has been purchased by Thomson Micromedex and it is our understanding that the

name “USP–DI” may not be used after 2007.)

Section 6001(f)(1) of the Deficit Reduction Act of 2005 (Pub. L. 109–171) (DRA) amends both “sections 1927(g)(1)(B)(i)(II) and 1861(t)(2)(B)(ii)(I) of the Act by inserting “(or its successor publications)” after ‘United States Pharmacopeia Drug Information’.” We interpret this DRA provision as explicitly authorizing the Secretary to continue recognition of the compendium currently known as USP–DI after its name change if the Secretary determines that it is in fact a successor publication rather than a substitute publication.

b. Requests To Amend the Compendia Listings

We received requests from the stakeholder community for recognition of additional compendia under the following authorities:

- Section 1861(t)(2)(B) of the Act which allows the Secretary to identify additional authoritative compendia; and
- Section 1873 of the Act which allows the Secretary to recognize a successor publication if one of the statutorily-named compendia changes its name.

In contrast, others suggested that the Secretary consider elimination of certain listed compendia. However, as we stated in the CY 2008 PFS proposed rule (72 FR 38177), there was no established regulatory process by which we could accept and act definitively on such requests. In addition, we saw the need to increase transparency of decision making criteria.

c. Technology Assessment of Drug Compendia Used To Determine Medically-Accepted Uses of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen

We commissioned a technology assessment (TA) from the Agency for Healthcare Research and Quality (AHRQ) on the currently listed compendia (AHFS and USP–DI), as well as other compendia (that is, National Comprehensive Cancer Network (NCCN), ClinPharm, DrugDex, Facts & Comparisons (F&C)) which might provide comparable information. AHRQ contracted the TA to the New England Medical Center (NEMC) and Duke Evidence-based Practice Centers (EPCs) and found little agreement in the evidence cited among drug compendia. In addition, the TA found little agreement between the EPCs’ independent identification of evidence on 14 example off-label indications and evidence cited in the drug compendia. The TA can be found at [http://](http://www.cms.hhs.gov/mcd/viewtechassess.asp?where=index&tid=46)

www.cms.hhs.gov/mcd/viewtechassess.asp?where=index&tid=46.

d. Medicare Evidence Development and Coverage Advisory Committee (MedCAC)

On March 30, 2006, the MedCAC (formerly the Medicare Coverage Advisory Committee (MCAC)) met in public session to advise CMS on the evidence about the desirable characteristics of compendia to determine medically-accepted indications of drugs and biologicals in anti-cancer therapy and the degree to which the currently listed and other available compendia display those characteristics. All information on this MedCAC meeting can be found on the CMS Web site at <http://www.cms.hhs.gov/mcd/viewmccac.asp?where=index&mid=33>. The agenda included a presentation of the TA performed for AHRQ by staff of the NEMC and Duke EPCs, scheduled stakeholder presentations, as well as an opportunity to hear testimony from members of the audience. As is customary, the MedCAC panelists elicited additional information from the presenters and discussed the evidence in preparation for a formal vote.

The MedCAC identified the following desirable characteristics:

- Extensive breadth of listings.
- Quick processing from application for inclusion to listing.
- Detailed description of the evidence reviewed for every individual listing.
- Use of pre specified published criteria for weighing evidence.
- Use of prescribed published process for making recommendations.
- Publicly transparent process for evaluating therapies.
- Explicit “Not recommended” listing when validated evidence is appropriate.
- Explicit listing and recommendations regarding therapies, including sequential use or combination in relation to other therapies.
- Explicit “Equivocal” listing when validated evidence is equivocal.
- Process for public identification and notification of potential conflicts of interest of the compendia’s parent and sibling organizations, reviewers, and committee members, with an established procedure to manage recognized conflicts.

The MedCAC concluded that none of the compendia fully display the desirable characteristics. The voting results can be viewed at the same Web site provided previously for the MedCAC meeting. In addition the MedCAC noted significant variability among the compendia. There was no

agreement among the panel members that any particular predetermined number of compendia was desirable.

Participants in the meeting also discussed the clinical usefulness of drug compendia in the treatment of cancer. It was reported that oncologists do not rely on compendia when making treatment decisions, relying instead on published treatment guidelines, clinical trial protocols, or consultation with peers.

Prior to the CY 2008 PFS proposed rule, we received, and reviewed, unsolicited comments from professional societies regarding additions and deletions to the listing of compendia for purposes of section 1861(t) of the Act. We received 46 public comments regarding these provisions on the CY 2008 PFS proposed rule.

2. Process for Determining Changes to the Compendia List

A compendium for the purpose of this section is defined as a comprehensive listing of FDA-approved drugs and biologicals or a comprehensive listing of a specific subset of drugs and biologicals in a specialty compendium, for example, a compendium of anti-cancer treatment. A compendium: (1) Includes a summary of the pharmacologic characteristics of each drug or biological and may include information on dosage, as well as recommended or endorsed uses in specific diseases; (2) is indexed by drug or biological; (3) differs from a disease treatment guideline, which is indexed by disease. We believe that the use of compendia to determine medically-accepted indications of drugs and biologicals in the manner specified in section 1861(t)(2)(B)(ii)(I) of the Act is more efficiently accomplished if the information contained is organized by the drug or biological and if the listings are comprehensive.

We proposed an annual process, incorporating public notice and comment, to receive and make determinations regarding requests for changes to the list of compendia used to determine medically-accepted indications for drugs and biologicals used in anti-cancer treatment as described in section 1861(t)(2)(B)(ii)(I) of the Act. The specific details of the proposed process were outlined in PFS CY 2008 proposed rule (72 FR 38118). We received the following comments on our proposed process.

Comment: Several commenters remarked that we should correlate Part B and Part D compendia for consistency within the Medicare program.

Response: The Social Security Act separately determines the Agency’s use

of authoritative compendia for specific programs. The use of any compendium for Part D or for Medicaid is beyond the scope of this regulation.

Comment: Many commenters voiced concerns about the time line proposed by CMS to address requests for changes to the list of compendia.

Response: We are striving to achieve a more expedient and predictable time line that will better serve the needs of those who care for Medicare beneficiaries. We have carefully considered the comments and made the following revisions:

(1) In order to shorten the proposed timeline, CMS will not publish an annual notice for formal requests.

(2) We expect to receive requests annually during a 30-day window starting January 15th.

(3) We expect to post these complete requests received by March 15th for public notice and comment on the CMS Web site.

(4) We will accept public comments for a 30 day period beginning on the day that the request is posted by CMS on the Web site.

Comment: Some commenters suggested alternative review cycles including changing the annual review to: a rolling review process; an every 3-year review process; or an every 5-year review process.

Response: We appreciate the commenters' suggestions regarding alternative review cycles; however, at this time, we believe that an annual review cycle is the best balance of these suggestions to promote a publicly responsive review process. Due to the general stability of the compendium publishing market, an annual review process is sufficient. However, if we determine that the public interest would be served by an immediate compendia review, we reserve the right to internally generate a request at any time.

Comment: Several commenters suggested specific additions to the list of compendia.

Response: The addition or deletion of specific compendia is beyond the scope of this regulation. Formal requests for additions and deletions may be submitted during the annual open request period established in this final rule with comment period.

Comment: The comments received from several associations and manufacturers stated that the language used for the individual desirable characteristics was not clear and that we did not give the appropriate consideration to quality concerns and the potential conflicts of interest.

Response: We appreciate the commenters' concerns and strive to

provide clarity on the MedCAC desirable characteristics that we will utilize in the compendia review process. The characteristics presented here represent an evidence-based consensus from the MedCAC panel on the desirability and priority of those characteristics. We recognize that different compendia might attempt to achieve these characteristics in individualized ways. CMS plans to use the desirable characteristics as framework and guidance in the review process. However, we believe that the public interest is best served by CMS attention to the quality and the integrity of each compendium's evidence evaluation process.

Comment: A few commenters made the general suggestion for CMS to prioritize the desirable characteristics identified at the MedCAC meeting, March 2006.

Response: We wish to clarify that the desirable characteristics recommended by the MedCAC will serve as guidance and a framework which will aid in the CMS review process. As stated in the CY 2008 PFS proposed rule, we "may consider additional reasonable factors in making a determination" as deemed appropriate. While we have decided not to rank the MedCAC desirable characteristics, we do consider the characteristics referencing transparency and conflict of interest to be of high priority to preserve the integrity and minimize bias during the review process.

Comment: Some commenters stated that a deletion from the list of compendia could cause a beneficiary to lose coverage of an off-label treatment regimen already begun.

Response: We understand the concern expressed by the commenters on a beneficiary's loss of coverage during the continuance of off-label treatment in the absence of compendium support; however local contractors have additional authority to make determinations regarding medically accepted indications. While we require local contractors to use the compendia as a reference in the determination of "medically-accepted" off-label treatment regimens, the compendia are not the sole reference for these determinations. Section 1861(t)(2)(B)(ii)(II) of the Act provides that local contractors use "supportive clinical evidence in peer-reviewed medical literature" to aid in making determinations of "medically-accepted" off-label treatment regimens when appropriate.

Comment: Commenters asked that we recognize compendia indexed by disease.

Response: In order to meet our criteria, a compendium should: (1) Include a summary of the pharmacologic characteristics of each drug or biological and may include information on dosage, as well as recommended or endorsed uses in specific diseases; (2) be indexed by drug or biological; (3) differ from a disease treatment guideline, which is indexed by disease. We believe that the use of compendia to determine medically-accepted indications of drugs and biologicals in the manner specified in section 1861(t)(2)(B)(ii)(I) of the Act is more efficiently accomplished if the information contained is organized by the drug or biological and if the listings are comprehensive.

Comment: Several commenters suggested that we should regulate a time frame for compendia to update their recommendations.

Response: We believe that the public interest is served if compendia generally update their recommendations in a timely manner when new evidence regarding the use of drugs warrants an update. We also believe that this is consistent with spirit of the MedCAC's recommendations. However, medical evidence on a particular use of a specific drug may at times be complex and inconsistent, and thus, merit a prolonged rather than an expedited analysis. We do not believe that we should establish in regulation a specific broad time line requirement at this time. However, we will consider public input regarding a compendium's timely updating of its recommendations as an additional criterion in our compendium review process.

Comment: We received comments suggesting that a compendium's use of grades of evidence may add a confusing factor in determining whether a compendium citation supports a particular drug use. Commenters stated that it is desirable for a compendium to clarify in a summary recommendation whether it regards each drug use as medically-accepted.

Response: We recognize and support the desirability of an explicit summary recommendation for each drug or biological cited in each compendium. This will facilitate the consistent interpretation of off-label recommendations by Medicare contractors.

Comment: One commenter suggested that a recognized compendium should include and identify a well designed clinical trial that is pending FDA approval.

Response: We do not believe that we can specify how a compendium

references materials regarding clinical trials for a drug not yet FDA-approved.

Comment: Two commenters claimed that section 1861(t)(2) of the Act mandates separate processes for adding and removing compendia.

Response: While we appreciate the thoughtful interpretation of the language, we do not agree separate processes are required by the statute.

Comment: One commenter suggested that the identity of the members of the compendium's advisory board and scientific review committee should become public record. The commenter also requested that we to establish a formal process to facilitate stakeholder/compendia communication.

Response: Public identification of members of the compendium's advisory board and the scientific review committees and establishing a formal process for stakeholders/compendia communication is beyond our authority and scope of this regulation.

Based on the public comments received, we have made revisions to the proposed compendia review process. We appreciate the need for a more expedient process to provide a useful compendia list for Medicare providers and have made the necessary changes.

Requests may be submitted in two ways (no duplicates please). Electronic submissions are encouraged to facilitate administrative efficiency. We will identify the electronic address to be used for submissions. Hard copy requests can be sent to the Centers for Medicare & Medicaid Services, Coverage and Analysis Group, Mailstop C1-09-06, 7500 Security Boulevard, Baltimore, MD, 21244. Please allow sufficient time for hard copies to be received prior to the close of the receipt period.

We may consider additional reasonable factors in making a determination. (For example, we may consider factors that are likely to impact the compendium's suitability for this use, such as but not restricted to a change in ownership or affiliation, suspension of publication, the standards applicable to the evidence considered by the compendium, and any relevant conflicts of interest. We may consider that broad accessibility by the general public to the information contained in the compendium may assist beneficiaries, their treating physicians, or both, in choosing among treatment options.)

- We will also consider a compendium's grading of evidence used in making recommendations regarding off-label uses and the process by which the compendium grades the evidence.

- We may, at our discretion, combine and consider multiple requests that refer

to the same compendium, even if those requests are for different actions. This facilitates administrative efficiency in our review of requests.

- We will notify the public of additions or deletions to the list of compendia on the CMS Web site.
- In keeping with our desire to shorten the compendia review time line, we will publish our decision no later than 90 days following the close of the public comment period.

M. Physician Self-Referral Issues

1. General

In the CY 2008 PFS proposed rule (72 FR 38122), we proposed several revisions to the physician self-referral regulations. We also solicited comments regarding potential changes to or limitations on the use of the in-office ancillary services exception in § 411.355(b). We received approximately 1100 pieces of timely correspondence in response to these proposals.

We received the following comments regarding finalizing our proposals:

Comment: Many commenters were concerned about the perceived complexity and breadth of the physician self-referral proposals. Several commenters questioned our ability to analyze sufficiently, and give adequate consideration to, the public comments due to the brief time period between issuance of the CY 2008 PFS proposed rule (72 FR 38122) and the statutory deadline for publication of this final rule with comment period. Some commenters suggested that we not finalize any of the proposals at this time. Many of those commenters asserted that we should further contemplate the issues and propose revised regulatory provisions in the CY 2009 PFS proposed rule if we continue to believe that such revisions are necessary.

Response: We are not inclined to follow the commenters' suggestion regarding reproposal of the physician self-referral provisions in the CY 2009 PFS proposed rule. However, given the number of physician self-referral proposals, the significance of the provisions both individually and in concert with each other, and the volume of public comments, we do not believe it is prudent to finalize any of the proposals in this rule (except for the proposal for anti-markup provisions for diagnostic tests, as discussed below in this section). Although we are not finalizing the proposed revisions to the other physician self-referral regulations in this final rule with comment period, we are confident that we have sufficient

information, both from the commenters and our independent research, to finalize revisions to the physician self-referral regulations without the need for new proposals and additional public comment. We intend to publish a final rule that addresses the following proposals:

- Burden of proof;
- Obstetrical malpractice insurance subsidies;
- Unit-of-service (per-click) payments in lease arrangements;
- The period of disallowance for noncompliant financial relationships;
- Ownership or investment interests in retirement plans;
- "Set in advance" and percentage-based compensation arrangements;
- "Stand in the shoes" provisions;
- Alternative criteria for satisfying certain exceptions; and
- Services furnished "under arrangements." Because we did not make a specific proposal regarding the in-office ancillary services exception, but rather merely solicited comments regarding its scope and application, any revisions to the exception in § 411.355(b) will be accomplished through a future notice of proposed rulemaking with provisions for public comment.

A measured, thoughtful approach to the final physician self-referral rules is critical. We believe that the future rulemaking will address the public comments and present a coordinated, comprehensive approach to accomplishing the goals described in the proposed rule, namely, minimizing the threat of program and patient abuse while providing sufficient flexibility to enable those who are parties to financial arrangements to satisfy the requirements of, and remain in compliance with, the physician self-referral law and the exceptions thereto.

2. Changes to Reassignment and Physician Self-Referral Rules Relating to Diagnostic Tests (Anti-Markup Provisions)

Medicare regulations currently prohibit the markup of the technical component (TC) of certain diagnostic tests that are performed by outside suppliers and billed to Medicare by a different individual or entity (§ 414.50). In addition, Medicare program instructions restrict who may bill for the professional component (PC) (the interpretation) of diagnostic tests (Section 30.2.9.1 of the CMS Internet-Only Manual, Publication 100-04, Medicare Claims Processing Manual, Chapter 1, general billing requirements, as amended or replaced from time to time).