the MNT codes which are paid only for 15-minute individual sessions and 30-minute group sessions. We also received a comment concerning the inputs for supplies and equipment. In addition, commenters stating the proposed payment rates were too low to enable rural providers of services to furnish KDE.

Response: As a result of the comments we received and our own further analysis, we have adjusted the payment rates for G0420 and G0421 to reflect the 1-hour time limit for a session. We have multiplied the work RVUs for G0420 by four and the work RVUs for G0421 by two to account for the fact that we are crosswalking a 15 minute code to a 60 minute code (CPT code 97802 to G0420) and a 30 minute code to a 60 minute code (CPT code 97804 to G0421). We also adjusted the inputs for supplies. However, we did not do a straight multiplication of the actual inputs because we do not believe the required equipment and supplies would increase in direct proportion to the time for the codes. We did not increase the inputs for the body analysis machine and the printer and scale for use during the session. However, we did increase the inputs for equipment and supplies for the use of the table, computer, paper and other printed materials because regardless of how long the session is, it takes only 5 minutes to use the body/mass index item, 2 minutes to weigh the individual, and 2 minutes to use the printer (this time equals the number of pieces of paper).

Comment: A commenter stated that a significant portion of kidney education is about nutrition and diet and that the MNT benefit includes provisions of MNT to patients with kidney disease. Therefore, some kidney education is already being provided to Stage IV kidney patients through the MNT benefit and it would be inappropriate to pay four times more for nutrition education when it is provided under the MNT benefit than when the exact same education is provided under the kidney education benefit. The commenter also stated that MNT is provided by dieticians and KDE is provided by physicians and midlevel practitioners and the new G-codes should be cross-walked to the ''all physicians'' PE and not to the registered dieticians PE.

Response: As stated, we did adjust the inputs for supplies and equipment to eliminate any duplication. We also cross-walked the ''all physicians'' PE to HCPCS codes G0420 and G0421 at the mid-level office visit.

In summary, we are finalizing the proposed HCPCS codes G0420, *Face-to-face educational services related to the care of chronic kidney disease; individual, per session, per one hour,* and G0421, *Face-to-face educational services related to the care of chronic kidney disease; group, per session, per one hour,* for KDE with the adjustments noted above. Refer to the Addendum B for the specific RVUs for G0420 and G0421.

12. Section 153: Renal Dialysis Provisions

Section 153 of the MIPPA requires changes to ESRD facilities for ESRD services effective January 1, 2010. The following is a summary of these changes.

Section 153(a)(1) of the MIPPA increases the current ESRD composite rate by 1.0 percent for services furnished on or after January 1, 2010. This also requires us to update the adjusted drug add-on. Since we compute the drug add-on adjustment as a percentage of the composite rate, the drug add-on percentage is decreased to account for the higher CY 2010 composite payment rate and results in a 15.0 percent drug add-on adjustment for CY 2010. As a result, the drug add-on amount of $20.33 per treatment remains the same for CY 2010, which results in a 15.0 percent increase to the base composite payment rate of $135.15 (see section II.I of this final rule with comment).

The composite rate paid to hospital-based facilities will be the same as the composite rate paid to independent renal dialysis facilities for services furnished on or after January 1, 2010, as required by section 153(a)(2) of the MIPPA. In addition, section 153(a)(2) of the MIPPA requires that in applying the geographic index to hospital-based facilities, the labor share shall be based on the labor share otherwise applied for renal dialysis facilities.

These MIPPA provisions are self-implementing and require no substantive exercise of discretion on the part of the Secretary. A detailed discussion of the MIPPA provisions can be found in section III. of the CY 2009 PFS final rule with comment period (73 FR 69881).

The following is summary of the comments we received regarding section 153 of the MIPPA.

Comment: One commenter supports the composite payment rates for both independent and hospital-based facilities be site neutral, and urges CMS to ensure that pediatric facilities are not adversely impacted by this adjustment.

Response: Section 153(a)(2) of the MIPPA requires the composite payment rate for both independent and hospital-based facilities to be site neutral and does not negatively impact pediatric facilities because, in addition to the composite payment rate, all pediatric facilities including hospital-based facilities are paid the basic case-mix adjustment of 1.62 for pediatric patients.

13. Section 182(b): Revision of Definition of Medically-Accepted Indication for Drugs; Compendia for Determination of Medically-Accepted Indications for Off-Label Uses of Drugs and Biologicals in an Anti-cancer Chemotherapeutic Regimen

a. Background

(1) Process for Revising the List of Statutorily Named Compendia

Generally, compendia are ''pharmacopeia providing information on drugs, their effectiveness, safety, toxicity, and dosing and are frequently used to determine whether a medication has a role in the treatment of a particular disease; these roles include both therapeutic uses approved by the U.S. Food and Drug Administration (FDA) and off-label indications'' (Agency of Healthcare Research and Quality (AHRQ), *Potential Conflict of Interest in the Production of Drug Compendia* White Paper).[2] Compendia are published by various institutions and by traditional reference book publishing houses.

Compendia publishers, including internal editorial staff and external experts, review requests received for the inclusion of recommendations regarding off-label uses of drugs or biologicals in anticancer regimens. These requests may be internally generated by the publisher or may be received as requests from external parties. The publisher reviews evidence related to the request and reaches a disposition of the request.

Section 1861(t)(2)(B)(ii)(I) of the Act lists the following compendia as authoritative sources for use in the determination of a ''medically-accepted indication'' of drugs and biologicals used off-label in an anti-cancer chemotherapeutic regimen: American Medical Association Drug Evaluations (AMA–DE); United States Pharmacopoeia-Drug Information (USP–DI) or its successor publication; American Hospital Formulary Service-Drug Information (AHFS–DI); and other authoritative compendia as identified by the Secretary. Due to changes in the pharmaceutical reference industry, AHFS–DI was the only statutorily

[2] Agency for Healthcare Research and Quality. White Paper: Potential Conflict of Interest in the Production of Drug Compendia. (2009, April 27). Available online at *http://www.cms.hhs.gov/mcd/viewtechassess.asp?from2=viewtechassess.asp&where=index&tid=64&*.

named compendium in current publication in CY 2008.

Section 1861(t)(2)(B) of the Act provides the Secretary the authority to revise the list of compendia in section 1861(t)(2)(B)(ii)(I) for determining medically-accepted indications for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen. Consequently, in § 414.930, we established an annual process to revise the list and a definition of ''compendium'' in the CY 2008 PFS final rule with comment period (72 FR 66222, 66303 through 66306, and 66404).

Currently, four compendia are recognized for purposes of section 1861(t)(2) of the Act: National Comprehensive Cancer Network Compendium, Gold Standard Clinical Pharmacology, Thompson Micromedex DrugDex, and AHFS–DI.

In addition to these compendia, the statute provides an alternative method for identifying medically-accepted off-label uses of drugs and biologicals in an anti-cancer chemotherapeutic regimen. Section 1861(t)(2)(B)(ii)(II) of the Act provides that local contractors may use ''supportive clinical evidence in peerreviewed medical literature'' to make such determinations. Thus these medically-accepted uses could be identified even if there were no compendia recognized for this purpose. We discussed this in our response to comments in the CY 2008 PFS final rule with comment period (72 FR 66305).

(2) Statutory Amendment

Section 182(b) of the MIPPA amended section 1861(t)(2)(B) of the Act (42 U.S.C. 1395x(t)(2)(B)) by adding the sentence, ''On and after January 1, 2010, no compendia may be included on the list of compendia under this subparagraph unless the compendia has a publicly transparent process for evaluating therapies and for identifying potential conflicts of interests.''

As discussed in the proposed rule, we proposed revisions to the compendia standards to implement the MIPPA amendments. We note that the publishers of the four compendia that are currently recognized for purposes of section 1861(t)(2) of the Act have already adopted conflict of interest disclosure policies that are similar to our proposal. Though there are individual differences among the publishers, we note that these policies commonly include publication on the compendia publisher's Web site of the name of the individuals that participate in the compendia recommendation and the entity with which there is a significant relationship, the nature of the relationship (for example, salary, ownership, grant support), and the value of the relationship.

Additional information with respect to the conflict of interest policies of those compendia can be found on their Web sites.

In addition, there is a growing body of literature, including that from the Institute of Medicine (IOM),[3] that discusses the conflict of interest between research funding and research results. We believe that section 182(b) of the MIPPA is designed, in part, to address this issue in the compendia review process. For a detailed discussion of our proposals concerning conflict of interest, see the CY 2010 PFS proposed rule (74 FR 33620 through 33623).

b. Provisions of the Proposed Regulation

As discussed in the proposed rule, we believe that the implementation of this statutory provision that compendia have a ''publicly transparent process for evaluating therapies and for identifying potential conflicts of interests'' is best accomplished by amending the current definition of a compendium at § 414.930(a) to include the MIPPA requirements and by defining the key components of publicly transparent processes for evaluating therapies and for identifying potential conflicts of interests.

In order to implement the MIPPA requirements concerning a publicly transparent process for evaluating therapies, we proposed that a compendium could meet this standard by publishing materials used in its evaluation process on its Web site. This mode of publication provides broad contemporaneous public access to relevant materials. We believe that public access to such materials will increase transparency of the process used by compendia publishers for evaluating therapies and facilitate independent review of recommendations by interested parties. In addition, as discussed in the CY 2008 PFS final rule with comment period (72 FR 66305 through 66306), such disclosure may assist beneficiaries and their physicians in choosing among treatment options.

In the CY 2010 PFS proposed rule (74 FR 33620 through 33623), we proposed the following amendments to § 414.930(a):

- To revise the definition of ''compendium'' by adding an additional requirement that a compendium have a publicly transparent process for evaluating therapies and for identifying potential conflicts of interests.
- To add a definition of a ''publicly transparent process'' for evaluating therapies whereby a compendium publisher would publish on its Web site the complete application for inclusion of a therapy including criteria used to evaluate the request; disclosure of the evidence considered; the names of the individuals who have substantively participated in the development of the compendia recommendations; and transcripts of meetings and records of votes for disposition of the request. We requested comments on the requirement for publication of the transcript and the suitability of other alternatives such as minutes or other documents.
- To add a definition of a ''publicly transparent process for identifying potential conflicts of interests'' whereby a compendium publisher would disclose by publication on its Web site information regarding potential conflicts of interests associated with individuals who are responsible for the compendium's recommendations, as well as their immediate family members. We requested comments on the suitability of this process or whether the compendia should prescribe their own process. The specific details of the proposed process were outlined in the proposed rule (74 FR 33621 through 33623). We received the following comments on our proposed revisions.

c. Public Comment and Response

Comment: Commenters generally agreed with the principle that conflicts of interest pose a risk to the integrity of compendia and should be minimized.

Response: We appreciate the general support for the principle.

Comment: Some commenters were concerned with the technological burden of maintaining disclosable information publicly on the compendia Web sites for a 5-year period.

Response: Public interest in the review and disposition of a request pertaining to a drug or biological may in some cases arise only after a drug or biological has been in widespread use for several years, during which its risks or adverse effects become apparent. In order to balance the burden on the compendia publishers with the public's interest in timely access to this information, we are revising our proposal to require that the publicly transparent process provide for disclosures to remain available on the compendium's Web site for not less than 3 years. However, for the reasons discussed in the proposed rule (see 74

[3] Institute of Medicine. Conflict of Interest in Medical Research, Education, and Practice. Available online at *http://www.nap.edu/catalog.php?record_id=12598.*

FR 33622 through 33623), the compendia should retain custody of the relevant information, enabling public access to the material upon request for not less than 5 years.

Comment: Commenters suggested that the burden of disclosing conflict of interest information regarding individuals who participate substantively in the review and disposition of multiple requests could be lessened if there were no requirement to separately disclose this information for each and every request.

Response: We recognize that some individuals may participate substantively in the review and disposition of more than one request. However, we also recognize that a single relationship may present a significant conflict of interest in some cases but not others. Therefore, we are requiring compendia in establishing a publicly transparent process for identification of potential conflicts of interest, to list the names of those individuals who substantively participated in the review or disposition of each request.

Comment: Some commenters were concerned that the immediate removal of a compendium that fails to meet the statutorily-mandated January 1, 2010 implementation date as specified by section 182(b) of the MIPPA would adversely impact a patient being treated with an off-label anti-cancer chemotherapeutic regimen based on a recommendation from that compendium. One commenter suggested grandfathering patients that began an off-label anti-cancer chemotherapeutic regimen based the recommendation of a compendium that is removed from the list of statutorily recognized compendia based on noncompliance with section 182(b) of the MIPPA.

Response: The statute provides an alternative method for identifying medically-accepted off-label uses of drugs and biologicals in an anti-cancer chemotherapeutic regimen. In accordance with section 1861(t)(2)(B)(ii)(II) of the Act, local contractors have additional authority to make determinations regarding medically-accepted indications. We discussed this in our response to comments in the CY 2008 PFS final rule with comment period (72 FR 66305).

Comment: A few commenters were concerned that the proposed publicly transparent process for evaluating therapies might be interpreted to apply only to externally generated requests received by compendia.

Response: We appreciate this comment and have clarified this provision, because in some instances, a compendium's determination is internally generated. Therefore, we have added text to clarify that the requirements pertain to an internally or externally generated request.

Comment: Some of the commenters were concerned that requiring transcripts would inhibit discussion amongst compendia recommendation decision makers and would be too burdensome to compendia publishers because of the number or length of meetings, which may include discussion of topics beyond the request. The commenters suggested requiring minutes and voting records rather than transcripts. One commenter suggested that we delay the implementation of this requirement for up to 1 year.

Response: We agree that publication of minutes and voting records would be sufficient because it would provide public transparency regarding the evaluation of the therapy at issue. We also believe that this requirement can be implemented much more readily than the proposed requirement for transcripts.

Comment: A few commenters were concerned about the requirement for compendia to publicly transcribe all meetings pertaining to compendium recommendations. Specifically, some compendia publishers convene telephone conferences rather than meetings or have processes that isolate advisors from each others' recommendations.

Response: We have replaced the transcript requirement as noted above. However, this comment remains relevant as we have been made aware that some compendia publishers do not conduct actual meetings of individuals substantively involved in reviewing and reaching dispositions of requests and thus could not provide minutes of meetings. We believe that minutes of telephone conferences, to the extent that such conferences are used in the evaluation of the request, could also be used to demonstrate the evaluation process used by the compendia.

Comment: One commenter questioned the use of § 411.354 to define direct and indirect financial conflicts of interests.

Response: In the proposed rule, we stated that the process for identifying potential conflicts of interest should include disclosure of direct and indirect ''similar to those relationships identified in 42 CFR part 411.'' Compendia maintain discretion to develop their own definitions for direct and indirect financial conflicts of interests, however, the definitions included in 42 CFR part 411 are provided as a resource for compendia to use in the development of these definitions.

Comment: One commenter suggested that we establish a specific dollar value that would trigger disclosure of financial conflicts of interests that exceed some minimum amount.

Response: We are not requiring compendia to disclose a specific dollar amount. We have left it to the discretion of the compendia publisher as to whether a specific dollar value would be publicly disclosed.

Comment: Many commenters expressed support for the disclosure of the conflicts of interests of individuals who are responsible for the compendium's recommendations, as well as their *immediate family members*. There was concern from some commenters that the definition of immediate family member in § 411.351 (which includes, in part, relationships with a spouse, children, and grandparents) was too extensive.

Response: We agree with this comment and are amending the provision concerning the process for public disclosure of immediate family members to be less extensive and more consistent with the current FDA *Guidance for the Public, FDA Advisory Committee Members, and FDA Staff on Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees* released in August of 2008.

We have also amended the publicly transparent process for identifying potential conflicts to include a provision that requires compendia to have a process for collecting and maintaining conflict of interest information and disclosure, if requested by the public in lieu of publishing this information on their Web sites. We believe this strikes a reasonable balance between the individual's personal privacy and the public interest in transparency.

Comment: Some requestors asked if the regulatory requirements would apply to past requests that were received or under review by compendia publishers before January 1, 2010 that may have led to treatment recommendations that are published after that date.

Response: These provisions would not apply retroactively. However, the MIPPA provisions are effective on or after January 1, 2010. Thus, compendia are responsible for complying with these provisions with respect to requests received after the date.

d. Provisions of the Final Regulation

This final regulation amends § 414.930(a) to revise the definition of

compendium to add a requirement that a compendium have a publicly transparent process for evaluating therapies and for identifying conflicts of interests. We also define a publicly transparent process for evaluating therapies and for identifying conflicts of interests. The revised definitions read as follows:

• *Publicly transparent process for evaluating therapies* means that the process provides that the following information from an internal or external request for inclusion of a therapy in a compendium are available to the public for a period of not less than 5 years, which includes availability on the compendium's Web site for a period of not less than 3 years, coincident with the compendium's publication of the related recommendation:

(i) The internal or external request for listing of a therapy recommendation including criteria used to evaluate the request.

(ii) A listing of all the evidentiary materials reviewed or considered by the compendium pursuant to the request.

(iii) A listing of all individuals who have substantively participated in the review or disposition of the request.

(iv) Minutes and voting records of meetings for the review and disposition of the request.

• *Publicly transparent process for identifying potential conflicts of interests* means that the process provides that the following information is identified and made timely available in response to a public request for a period of not less than 5 years, coincident with the compendium's publication of the related recommendation:

(i) Direct or indirect financial relationships that exist between individuals or the spouse or minor child of individuals who have substantively participated in the development or disposition of compendia recommendations and the manufacturer or seller of the drug or biological being reviewed by the compendium. This publicly transparent process may include disclosure of, for example, compensation arrangements such as salary, grant, contract, or collaboration agreements between individuals or the spouse or minor child of individuals who have substantively participated in the review and disposition of the request and the manufacturer or seller of the drug or biological being reviewed by the compendium.

(ii) Ownership or investment interests between individuals or the spouse or minor child of individuals who have substantively participated in the development or disposition of compendia recommendations and the manufacturer or seller of the drug or biological being reviewed by the compendium.

H. Part B Drug Payment

1. Average Sales Price (ASP) Issues

a. Immunosuppressive Drugs Period of Eligibility

Before enactment of section 9335(c) of the Omnibus Budget Reconciliation Act of 1986 (Pub. L. 99–509) (OBRA '86), there was no specific Medicare benefit that provided for Medicare Part B coverage of prescription drugs used in immunosuppressive therapy. OBRA '86 added subparagraph (J) to section 1861(s)(2) of the Act to provide Medicare coverage for immunosuppressive drugs, furnished to an individual who receives an organ transplant for which Medicare payment is made, for a period not to exceed 1 year after the transplant procedure. Coverage of these drugs under Medicare Part B began January 1, 1987.

Section 13565 of the Omnibus Budget Reconciliation Act of 1993 (Pub. L. 103–66) amended section 1861(s)(2)(J) of the Act to allow eligible beneficiaries to receive additional Part B coverage within 18 months after the discharge date for immunosuppressive drugs furnished in 1995; within 24 months for immunosuppressive drugs furnished in 1996; within 30 months for immunosuppressive drugs furnished in 1997; and within 36 months for immunosuppressive drugs furnished after 1997. Beginning January 1, 2000, section 227 of the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 (Pub. L. 106–113) (BBRA) extended coverage to eligible beneficiaries whose coverage for drugs used in immunosuppressive therapy expires during the calendar year, an additional 8 months beyond the 36-month period.

Section 113 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (Pub. L. 106–554) (BIPA 2000) revised section 1861(s)(2)(J) of the Act to eliminate the time limits for coverage of prescription drugs used in immunosuppressive therapy under the Medicare program. Effective with immunosuppressive drugs furnished on or after December 21, 2000, there is no longer any time limit for Medicare benefits. This policy applies to all Medicare entitled beneficiaries who meet all of the other program requirements for coverage under this benefit. Therefore, for example, entitled beneficiaries who had been receiving benefits for immunosuppressive drugs under section 1861(s)(2)(J) of the Act, but whose immunosuppressive drug benefit was terminated solely because of the time limit described above, resumed receiving that benefit for immunosuppressive drugs furnished on or after December 21, 2000.

According to section 226A(b)(2) of the Act, ''ESRD only'' beneficiaries continue to lose their general Medicare coverage and, by extension, Part B coverage for immunosuppressive drug therapy 36 months after discharge from a hospital following a covered transplant. Beneficiaries will have Part B coverage for immunosuppressive drug therapy for as long as they remain eligible for Medicare.

Our proposal to codify the immunosuppressive drug coverage does not cause a substantive programmatic change since the provisions in section 113 of the BIPA 2000 eliminating the time limit from section 1861(s)(2)(J) of the Act are self implementing for services on or after December 21, 2000. We included this topic in the proposed rule in order to make conforming changes to the regulatory text at § 410.30. We proposed to amend paragraph (b) to codify the changes to the immunosuppressive drug coverage time limit as required by section 113 of the BIPA 2000.

The following is a summary of the comments we received and our responses:

Comment: We received a few comments which supported our proposal. Commenters noted that this technical change will reduce the potential for confusion in the future about the scope of Medicare coverage of and payment for immunosuppressive drug therapy.

Response: We appreciate the supportive comments and agree that any steps which reduce confusion benefit Medicare and its stakeholders.

After reviewing the public comments, we are finalizing our proposed revisions to § 410.30.

b. WAMP/AMP Threshold

Section 1847A(d)(1) of the Act states that ''the Inspector General of HHS shall conduct studies, which may include surveys to determine the widely available market prices (WAMP) of drugs and biologicals to which this section applies, as the Inspector General, in consultation with the Secretary, determines to be appropriate.'' Section 1847A(d)(2) of the Act states that, ''Based upon such studies and other data for drugs and biologicals, the Inspector General shall compare the ASP under this section for drugs and biologicals with—