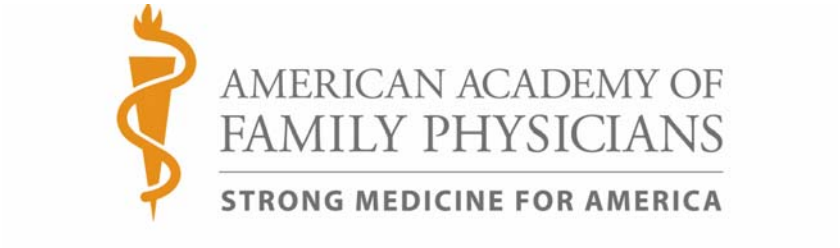

December 22, 2010

Donald Berwick, M.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1503-FC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Dr. Berwick:

I am writing on behalf of the American Academy of Family Physicians (AAFP), which represents over 94,700 physicians and medical students nationwide. Specifically, I am writing to offer our comments on the final rule with comment period regarding payment policies under the Medicare physician fee schedule and other revisions to Medicare Part B for calendar year 2011. The Centers for Medicare and Medicaid Services (CMS) published the final rule in the *Federal Register* on November 29, 2010, and invited comments on the interim final work, practice expense, and malpractice relative value unit (RVUs) for the Current Procedural Terminology (CPT) codes listed in Addendum C of the final rule.

General Comments

Before addressing the interim RVUs that CMS has assigned to specific codes in Addendum C of the final rule, we do want to recognize and thank CMS for its ongoing effort to address primary care issues within the parameters permitted by the current statute. This effort was evident in a number of provisions of the final rule.

For instance, in response to comments submitted by the AAFP and others, CMS made some significant adjustments to the Primary Care Incentive Program (PCIP) that will help ensure a greater percentage of primary care physicians qualify for the incentive. In fact, CMS estimates that over 80 percent of physicians who currently are enrolled in Medicare with a primary specialty designation of family medicine will qualify for the PCIP based on calendar year 2009 claims data.

We want to encourage the agency to continue this effort. Millions of Americans will become eligible for Medicare in the near future, and implementation of health care

reform will provide greater access to health care for millions more Americans during the same time frame. In this context, primary care will be essential to ensure that the needs of these individuals are met. The appropriate valuation of individual physician services, as addressed in our comments below, is an important piece of this larger puzzle of adequate payment for primary care physicians. It therefore remains vitally important for CMS to keep its eye on the larger picture, not just the physician fee schedule. Anything that CMS can do to support primary care will benefit the program, its beneficiaries, and other Americans as well.

Comments on Codes in Addendum C

Immunization Administration (CPT Code 90460 and 90461)

The AAFP is very disappointed that CMS decided to disagree with the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC) valuation recommendations for the new immunization administration codes, 90460 and 90461. During its February 2009 meeting, the RUC recommended that the codes be valued as follows:

> **90460** *Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified healthcare professional; first vaccine/toxoid component*
> **RUC Recommended Work Relative Value Units (RVUs) = 0.20**
>
> **90461** *Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified healthcare professional; each additional vaccine/toxoid component*
> **RUC Recommended Work Relative Value Units (RVUs) = 0.16**

CMS decided to "assign alternative values of 0.17 work RVUs to CPT code 90460 and 0.15 work RVUs to CPT code 90461 on an interim basis for CY 2011." CMS states that it disagrees with the RUC recommendations since the new codes "would be billed on a per toxoid basis," even though they acknowledge that the RUC's reasons for recommending an increase in work RVUs is "due to increased time for patient education."

The rationale for revising the immunization administration codes was based on the fact that the per administration predecessor codes did not allow physicians to accurately report the considerable work involved in counseling for combination vaccines (i.e., those vaccines with more than one component). The new codes represent a substantial structural revision from their predecessor codes in that they allow reporting of counseling per vaccine component rather than per administration. It is inappropriate to crosswalk values from predecessor codes to the new codes given the underlying structural differences between the two sets of codes.

Furthermore, CMS's crosswalk valuation for the new codes would make the relative value of physician work equivalent to other immunization administration codes (i.e., 90471-90472), which do not have the requirement of physician counseling as part of their descriptors. We note that, on Sunday, December 5, 2010, a full-page advertisement appeared in many of America's major newspapers extolling the benefits and necessity of obtaining the seasonal influenza vaccine. This advertisement was sponsored by the Department of Health and Human Services and the Centers for Disease Control and Prevention. Over 40 medical and medically associated organizations prominently signed on as supporters of this effort. It is therefore both somewhat ironic and very disappointing, that, at the same time you are promoting immunizations with the very public support of those organizations that actually provide this service, you have taken such an approach in valuing these services. Unfortunately, it is action such as this that contributes to a sense among our members that CMS continues to under-appreciate and therefore undervalue the work that primary care physicians in general and family physicians in particular provide, despite the agency's efforts noted above. Accordingly, we request that CMS reconsider its interim work RVUs for codes 90460 and 90461 and accept the corresponding RUC recommendation in both cases.

Subsequent Hospital Observation Care

At its June 2009 meeting, the CPT Editorial Panel approved three new codes to report subsequent observation services in a facility setting. These codes are:

- 99224 (Level 1 subsequent observation care, per day);
- 99225 (Level 2 subsequent observation care, per day); and
- 99226 (Level 3 subsequent observation care, per day).

The RUC reviewed survey data for code 99224 and accepted the following physician times: 5 minutes of pre-service, 10 minutes of intra-service and 5 minutes of post-service time. The RUC believed this code was comparable in physician time and intensity to CPT code 99231 (Level 1 subsequent hospital care, per day, for the evaluation and management of a patient), and recommended work RVUs of 0.76.

Similarly, the RUC reviewed the survey data for code 99225 and accepted the following physician times: 9 minutes of pre-service, 20 minutes of intra-service and 10 minutes of post-service time. The AMA RUC believed this code was comparable in physician time and intensity to CPT code 99232 (Level 2 subsequent hospital care, per day, for the evaluation and management of a patient), and recommended work RVUs of 1.39.

Finally, the RUC reviewed the survey data for code 99226 and accepted the following physician times: 10 minutes of pre-service, 30 minutes of intra-service and 15 minutes of post-service time. The AMA RUC believed this code was comparable in physician time and intensity to CPT code 99233 (Level 3 subsequent hospital care, per day, for the evaluation and management of a patient), and recommended work RVUs of 2.00.

In the final rule, CMS states:

> Observation services are outpatient services ordered by a patient's treating practitioner. Admission of the patient to the hospital as an inpatient or the ending of observation services must also be ordered by the treating practitioner. CMS has stated that in only rare and exceptional cases would reasonable and necessary outpatient observation services span more than 48 hours. In the majority of cases, the decision whether to discharge a patient from the hospital following resolution of the reason for the observation care or to admit the patient as an inpatient can be made in less than 48 hours, usually in less than 24 hours. Consequently, we believe that the acuity level of the typical patient receiving outpatient observation services would generally be lower than that of the inpatient level. We believe that if the patient's acuity level is determined to be at the level of the inpatient, the patient should be admitted to the hospital as an inpatient. We note that CMS has publicly stated in a recent letter to the AHA that ''it is not in the hospital's or the beneficiary's interest to extend observation care rather than either releasing the patient from the hospital or admitting the patient as an inpatient . . . .''

Consequently, CMS is not accepting the RUC's recommendation to value the subsequent observation care codes at the level of subsequent inpatient hospital care services. Instead, to recognize perceived differences in patient acuity between the two settings, CMS removed the pre- and post-services times from the RUC recommended values for subsequent observation care, reducing the values to approximately 75 percent of the values for the subsequent hospital care codes. Thus, CMS is assigning alternative work RVUs of 0.54 to code 99224, 0.96 to code 99225, and 1.44 to code 99226 on an interim final basis for CY 2011.

We take exception to CMS's valuation of these codes on several grounds. First, CMS's statement that "in only rare and exceptional cases would reasonable and necessary outpatient observation services span more than 48 hours," ignores the fact that the incidence of observation services extending beyond 48 hours doubled between 2006 and 2008. As CMS Acting Administrator and Chief Operating Officer, Marilyn Tavenner, wrote to the President and Chief Executive Officer of the American Hospital Association (AHA) on July 7, 2010, CMS:

> . . . has become increasingly concerned that Medicare beneficiaries are remaining in observation care for longer periods of time, sometimes exceeding 48 hours. Our claims data indicate a modest trend toward proportionally more observation services extending beyond 48 hours, from approximately 3 percent in 2006 to nearly 6 percent in 2008.

Second, CMS's statement that "the acuity level of the typical patient receiving outpatient observation services would generally be lower than that of the inpatient level" is an assumption, not a documented statement of fact. In fact, hospital inpatient and outpatient status is often as much a function of payment policy as it is patient acuity. That is,

hospitals not infrequently declare a patient's status as "inpatient" or "outpatient" based on what they calculate will be most financially advantageous (e.g., based on a comparison of what Medicare will pay under the outpatient versus inpatient prospective payment systems), which does not necessarily equate to patient acuity. Thus, a patient kept in observation as an outpatient for 23 hours may be as sick or sicker, and require as much or more physician work, than a patient admitted as an inpatient for the same time period.

If hospitals were not gaming the system in this regard, there would be no need for CMS to express the concern noted above to the AHA nor to remind the AHA ''it is not in the hospital's or the beneficiary's interest to extend observation care rather than either releasing the patient from the hospital or admitting the patient as an inpatient…'' Thus, CMS's correspondence with the AHA undermines the validity of the agency's assumptions in this regard.

Finally, we take exception to how the agency has attempted to value these subsequent observation codes. Removing the pre- and post-service time of each implies there is no such time or physician work involved, and it implies that subsequent observation care only involves face-to-face time with the patient. The reality is that subsequent observation care does involve physician time and work both before and after the encounter, just as almost all evaluation and management services do. Setting aside the acuity issue momentarily, we note that subsequent hospital codes 99231-99233 all involve pre- and post-service physician time and work. Even if patients in observation status were less acute, the need for pre- and post-service time and work would not simply disappear, as CMS suggests that it would.

In sum, we believe that in the current hospital care and payment environment, patients in observation status may be as acute as those who happen to be designated as "inpatient." We further believe that subsequent observation care involves physician time and work before and after the intra-service portion of the encounter. Therefore, we strongly urge CMS to review its assumptions and approach to valuing these codes and instead accept the RUC recommended values in each case.

Maternity Care Codes

As a result of being identified as potentially mis-valued codes by the RUC's Five-Year Review Identification Workgroup, the RUC reviewed the CPT codes that define maternity care. Several of these codes include ante-partum care and/or delivery as well as post-partum care for which the RUC recommended significantly increased work values. For post-partum care with delivery, which is included in all of these codes, the RUC recommended inclusion of one CPT code 99214 (Level 4 established patient office or other outpatient visit).

CMS disagrees with the RUC recommended work RVUs for these services and believes that one CPT code 99213 visit (Level 3 established patient office or other outpatient visit) more accurately reflects the services furnished for this post-partum care visit. Therefore, for codes that include post-partum care following delivery visits, CMS converted all CPT

code 99214 blocks to a CPT code 99213 visit and have revised the work RVUs accordingly.

Additionally, CMS applied a "work budget neutrality factor" of 0.8922 to all of the maternity care codes. In CMS's opinion, the aggregate increase in work RVUs for the maternity care services that would result from its adoption of the RUC recommended work RVUs (as modified above) is not indicative of a true increase in physician work for the services. Therefore, CMS believes it would be appropriate to apply work budget neutrality to this set of codes. In essence, CMS reduced the final work RVUs for each code in the family by approximately 11% to ensure that the aggregate work RVUs for the family would remain the same, even as the work RVUs within the family change.

We were very disappointed with the CMS response to the RUC's physician work recommendations for maternity care services (CPT codes 59400 to 59622). As you know, CMS asked that the RUC review the times and values of all codes with an "MMM" global period. The values for these codes were initially established by CMS in 1993 and 1995 without the use of valid survey instruments.

The RUC was not able to replicate the building block methodology that was described in the December 2, 1993, final rule. There was no explanation of the rationale used to assign the RVUs to management of labor or to the actual delivery. The value for in-hospital post-partum care was also not explained. Further, the original valuation did not seem to account for any discharge day management. The RUC concluded that the original assumption used to develop the work RVUs were incorrect, as are the current values. Nonetheless, the RUC agreed with the specialties that a building block approach would be the best way to evaluate these services, given the complexity of providing over nine months of care and reporting it in a single code, where appropriate.

The usual RUC survey instrument does not collect the information needed to value these services. Consequently, the AAFP and the American College of Obstetricians and Gynecologists (ACOG) worked with the RUC to develop a survey instrument that would collect the data needed to correctly value these services. The survey instrument asked physicians to provide information about the four parts of routine maternity care:

- Ante-partum Care
- Management of Labor
- Delivery Care
- Post Delivery Care

The RUC thoroughly vetted the recommendations from AAFP and ACOG. After extensive review, the RUC was able to agree on the recommendations that were submitted to CMS. The process was transparent, and the recommendations were reasonable. The building block methodology was thoroughly explained in the RUC recommendations that were sent to CMS.

Even managers of state Medicaid programs understand that the RVUs assigned to maternity care services are inadequate. According to a report by the Kaiser Family Foundation, 23 states pay more than the Medicare fee schedule amount for maternity care (Zuckerman S, Williams AF, Stockley KE. Trends in Medicaid physician fees, 2003-2008. Health Aff 2009; 28:w510-9).

In addition to undervaluing the total physician work for management of labor and delivery, CMS also suggested that the postpartum visit is equivalent to a 99213, rather than the 99214 recommended by the RUC.

The typical post-partum visit takes in excess of 40 minutes, and includes these activities:

> **History:** Comprehensive. History of present illness includes questions related to her labor and delivery and any difficulties she has experienced since discharge from the hospital. Medical and surgical complications encountered during the pregnancy, labor and delivery are reviewed. Discuss whether she is bottle feeding or breast feeding. Review of her last Pap smear.
> **Physical Exam:** Comprehensive single organ system exam.
> **Medical Decision Making:** High complexity.
> - Discuss maternal sleep patterns and any signs of post partum depression or anxiety.
> - Discuss the return of menses in both breast feeding and non breast feeding women and the risk of pregnancy prior to the return of menses.
> - Discuss risks and benefits to the various methods of contraception and decide what is appropriate.
> - Discuss spacing of pregnancies and risks of future pregnancies if she needs a repeat Cesarean delivery or VBAC.
> - Discuss the possible need for vaginal lubricants in breast feeding mothers or those who had vaginal stitches.
> - Discuss appropriate preventative medicine concerns including immunizations and follow-up as required regarding Pap smears, breast exams and mammograms.

This exceeds the CPT and CMS requirements for reporting Evaluation and Management (E/M) code 99214. If this visit were to be reported with an E/M code based on time, due to the extensive counseling provided, this visit meets the requirements for a 99215.

The physician community agrees that the resource-based relative value scale embodied by the Medicare physician fee schedule currently undervalues maternity care services. We encourage CMS to accept the RUC recommendations, without either adjusting the post-partum work or applying a budget neutrality adjustment to the family. The RUC-recommended values accurately reflect the physician work required to provide those services.

In closing, we appreciate this opportunity to comment on matters related to the Medicare Physician Fee Schedule. As always, the AAFP looks forward to working with CMS in its

continued efforts to ensure access to appropriate physician services. If you or your staff has any questions about our comments, please contact Mr. Robert Bennett, Federal Regulator Manager at the AAFP, at 1-800-274-2237, extension 2522, or at rbennett@aafp.org.

Sincerely,

Lori J. Heim, M.D., FAAFP
Board Chair