**Responses to Comments Received**

**Federal Register Notice on Revised**

**CMS-416 and Instructions**

CMS received two comments on the April 19, 2010, notice on the proposed changes to the form CMS-416 that reflect the changes required by Children’s health Insurance Program Reauthorization Act of 2009 (CHIPRA), as well as additional changes proposed by CMS and the Oral Health Technical Advisory Group (OTAG). The commenters were the Medicaid /SCHIP Dental Association (MSDA) and Arizona Health Care Cost Containment System, the Arizona Medicaid agency. Most of the comments were identical, therefore, CMS will respond to the comments together.

**Comments on Supporting Statement for the EPSDT Report Form CMS-416**

Two commenters noted that the proposed changes included two new lines of data that were required by CHIPRA. Both also noted that another CHIPRA requirement was the development of an initial core set of children’s health care quality measures. However, one commenter indicated that the proposed measure for children’s access to dental care (line 12a) does not allow an equitable comparison for States. Another commenter indicated that the additional lines of data (lines 12d and 12f) do not allow for equitable comparison of data between States. Both note that these issues are addressed later in their comments.

**CMS Response**

CMS will respond to these comments when specifically addressed later in this document as noted by the commenters.

**Justification**

Two commenters noted that the document indicates CMS uses the information collected on the CMS 416 to assess the effectiveness of State EPSDT programs including the provision of required dental services for eligible children. Both commenters indicate that the CMS 416 is not an adequate assessment of the effectiveness of States providing dental services because the variations in length of eligibility are not adequately taken into account in the measures proposed by CMS. Both indicate the variations skew the data and render them unreliable for purposes of comparing States or assessment national trends.

**CMS Response**

CMS acknowledges that the dental data collected on the CMS 416 is not a perfect measure of dental services. CMS has worked over the years to improve the data collected on the CMS-416 including the dental data. The data collected on the for CMS 416 is required by the statutory requirements of section 1905(a)(43)(D) of the Social Security Act (the Act). Specifically, the statute requires at section 1905(a)(43)(D)(iii) that States report the “**number of children receiving dental services**.” Based on this requirement to collect an aggregate number and with additional input from a dental workgroup consisting of States, dental advocates and federal representatives, in 1999, CMS expanded the dental data collected on the form to provide additional information on specific groups of dental services provided to children. Those changes included breaking out the dental data into three lines of data: 12.a. - Any dental services, 12.b. - Preventive services and 12.c. Treatment services. The rationale for this delineation of services was to better allow CMS, States and the public, to see the type of dental services that were actually being provided rather than just one aggregate number.

Based on discussions the OTAG over the past year and a half, CMS had been working on revisions to the CMS 416, prior to the implementation of CHIPRA. There was recognition that additional providers were furnishing dental/oral health services to eligible children. This data was not being reported which some States felt led to an undercount of the number of children receiving dental/oral health care services in their States. CMS worked with the OTAG members to propose an update the CMS 416 to best represent the services being provided by non-dentists such as pediatricians and independently practicing dental hygienists. While this work was occurring, the CHIPRA legislation was passed which required additional changes to the CMS 416, to collect data on dental sealants and to break out the number of children counted on the CMS 416 who are receiving services as part of a CHIP Medicaid expansion program. The decision was made not to move forward with the initial data changes so that it would not be unduly burdensome for States to revise their data reporting in two consecutive years.

CMS believes the dental data, while not perfect, does allow for comparison across States and does provide a basis for determination national trends, in part, because all States report the same CDT codes on the CMS 416. With respect to the comment that the variations in length of eligibility skews the data, CMS believes the addition of line 1.b, which uses the number of children eligible for 90 continuous days as the denominator, will address the variation across States. However, we will further address this aspect of the comment below in our response to the comment on line 1.b.

**Change in Burden**

Two commenters indicated that CMS assertion that there will be no significant change in burden to collect the additional information. Both commenters note that while this may be true for existing providers, fiscal intermediaries will be required if new data elements are added for which data are not currently being collected, i.e., dental services provided y non-dental providers. This will additional programming time will be an additional expense to States. One commenter also noted the unprecedented budget shortfalls many States are facing and other CMS directives (clinical outcomes measurement, meaningful use to support HER under ARRA 2009, and the CHIPRA quality improvement measures) States are undertaking. Adding new requirements for data collection and reporting will likely not yield significantly better data that can be used to drive quality improvement and will distract from initiatives already under way.

**CMS Response**

CMS understands the concerns that there are numerous activities involving Medicaid data being undertaken. However, many of these initiatives, such as the child health performance measures and the requirement to collect certain data on the CMS-416, were specified in recent legislation. Therefore CMS is required to make those changes in order to be in compliance with the law.

While CMS acknowledges that there will be programming changes needed in some States to collect the additional data included on the CMS-416, after several discussions with CMS System staff and States, we continues to believe that any additional burden on States to collect the new data is not significant. Certified State MMIS systems must be able to produce ad hoc reports with any data that exists in the system. In addition, States must have staff in place that can run any ad hoc reports. State are already collecting dental data and reporting by CDT code on the current CMS 416. The requirement that the data for dental sealants be reported on a different line (12.d) should not require significant changes or burden. In addition, States currently have available information on children’s eligibility criteria. Therefore reporting children eligible for EPSDT as part of a Medicaid CHIP expansion group should not be overly burdensome for a State to calculate.

The data to be collected on lines 12e-12f will be new data for most States to collect and report. This new data request may require some States to reprogram their systems to capture the provider type for the service. However, the provider type information should already be available to States so it would not appear to be a major undertaking for States to begin collecting and reporting this data.

**Comments on Revised Form CMS-416 Instructions**

**Purpose**

Two commenters noted that the instructions indicate that CMS uses the completed reports to look at trend patterns and projections for the nation and for individual States or geographic areas to make decisions and recommendations to ensure that eligible children are given the best possible health care. The commenters indicated that meaningful comparisons can only be made if the same data is collected and reported consistently by States. Neither the current methodology of using unduplicated counts of individuals eligible for EPSDT as the denominator for calculating utilization nor the proposed change to using counts of individuals eligible for EPSDT for at least 90 continues days recognizes that fact that children who are enrolled for 90 continuous days do not have the same opportunity to receive dental services as children enrolled for an entire year. Furthermore variation in length of eligibility across States precludes fair and equitable comparisons between them.

One commenter also recommended that CMS collect separate managed care data and fee for service data and report only managed care data if, for example, a State has 95 percent of its population in managed care and five percent in fee for service. This commenter also indicates that because the Medicaid and CHIP programs represent different populations they should not be combined into one report.

**CMS Response**

CMS believes the current method of counting all children, regardless of the length of eligibility, puts States in the position of including children on the CMS 416 who may have been eligible for one day or one month. The expectation of a child actually receiving a screening service in that period of time is low and puts the States at a disadvantage in calculating their screening and participation rates. The proposed Line 1.b added to the CMS 416 to report children eligible for EPSDT for 90 continuous days is primarily focused on the calculation of the State’s screening and participation goals related to screening services. While using this number will impact dental data in the determination of a utilization rate for services, it potentially improves a States utilization rate in that the same children not included for purposes of receiving screening services will also not be included in any dental calculation.

The inclusion of 90 continuous days of eligibility on the proposed CMS 416 was discussed on several occasions with the OTAG membership. There was not unanimous agreement on the use of the 90 continuous days or the use of the HEDIS measures. However, many of the OTAG membership indicated that the 90 days timeframe was a step in the right direction. In addition, CMS felt that moving from counting all children eligible for even one day to counting children only eligible for 11 of 12 months using the HEDIS criteria would have a substantial impact on the general health screening data reported and the screening and participation goals. CMS did not feel the OTAGs interest in using HEDIS should override our concerns for the data collected for EPSDT screens, which is the underlying purpose of the CMS 416 data collection.

We disagree with the comment on breaking out managed care and fee for service data and including only managed care data for States with most of their population in managed care arrangements. In States with this type of arrangement, EPSDT is still required to be provided to those eligible individuals under fee for service arrangements. In many cases, these are disabled or special needs children who are not required to be included in managed care arrangements. We do not believe they should be excluded from being counted on the CMS 416.

Finally, the only children that should be included on the CMS-416 are children eligible for EPSDT services. Children eligible under a separate CHIP program should never be included on the CMS 416 because they are not required to be provided EPSDT services. Only those children who are Medicaid eligible or receiving services through a CHIP Medicaid expansion program should be included on the CMS 416. CMS will revise the instructions for the form to specify this information.

**Effective Date**

Two commenters noted that it may be difficult for States to provide the additional information required since more than half the year is over and the revised form may require some States to reprogram their systems. The commenters recommended that States be given additional time to make system changes.

**CMS Comment**

CMS understands the concern regarding States that may not be able to report all the additional data for fiscal year 2010 in April 2011. While we agree there may be some States that need to reprogram some elements of their system, we also believe some of the data to be reported is already being collected and will not be unduly burdensome for States to report. Every State currently collects the data on dental sealants (line 12.d.) as part of the data reported on preventive dental services (line 12.b). We do not believe that States should have difficulty including this information on their submittals for 2011 as the only change will be reporting the data on a different line. In addition, States should already be able to differentiate their Medicaid eligibles from their CHIP Medicaid expansion population for inclusion on the form (line 1.c.) Therefore every State should report the sealant data and the eligibility data for fiscal year 2010 in April 2011.

The inclusion of data for services provided by non-dentists and data for diagnostic services were not changes required by CHIPRA and may require reprogramming of State systems to capture these codes. However, we believe States should already have a system in place which identifies not only the service provided but the provider of the service. We do not believe reporting this information should require substantial changes to a States system. However if this information is not available for States to report in April 2011 CMS would accept the States submittal without the information on diagnostic services and non-dental providers and allow the State to report complete data for fiscal year 2011. CMS would also accept an updated CMS 416 form from any State for FY 2010 if a State was able to report the data at a later date.

**Line 1.b. Total Individuals Eligible for EPSDT for 90 Continuous Days**

Two commenters noted that CMS recognizes the variation in the length of eligibility makes comparisons between States difficult and CMS has attempted to adjust for this by including a new requirement on the form to calculate and report the total number of children who have been eligible for at least 90 continuous days (line 1.b.). Both commenters note that the HEDIS dental measure, the HEDIS Annual Dental Visit, uses as its denominator the number of individuals continuously enrolled for 11 of the previous 12 months with no more than a 45-day break in eligibility and suggest CMS should use the same measure for the CMS 416 dental data. Both commenters also note that several of the proposed CHIP Core Measures use at least one year of continuous eligibility in their denominator suggests that this would also be acceptable for the CMS 416 and would allow direct comparisons between access to dental care and primary care as proposed in CHIPRA initial measure #24.

**CMS Response**

CMS acknowledges that in the future, other sources of data such as the core measure set may be used to measure access to children’s primary care and dental services. However, the core measure set is not currently sufficient to meet the statutory reporting requirements of EPSDT services nor is it mandatory for all States to use for reporting. In response to States’ concern over the years that using the total number of children eligible for EPSDT services, even for one day, as the denominator for the calculation on the form, CMS discussed options for updating this information the OTAG on several occasions. As noted earlier, the use of 90 days of continuous eligibility and the HEDIS method were both discussed. Most agreed there should be change but there was no consensus on one method over another.

CMS had several concerns with moving to HEDIS for the CMS 416. First, as noted in our earlier comment, CMS explained that while we understood the reasons for recommending the use of HEDIS measures for dental reporting, the information on eligibility on the CMS 416 is used primarily for calculating EPSDT screening and participation ratios, not dental utilization. Any change made to the way eligible children are reported could have a significant impact on a States screening and participation ratio and make comparability with prior years data impossible. In addition, while younger children are more likely to stay on the rolls continuously, older children may be more likely to go on and off the roles or not be eligible for a full year. However, these children are still entitled to EPSDT services and the States should be held accountable for providing those services. While several OTAG members were adamant about the use of HEDIS measures, most members agreed that moving to the 90 day continuous eligibility was a good first step in revising the form.

All States will benefit by eliminating those children who are eligible for brief periods of time (<90 days) and are unlikely to receive any services, general health screenings or dental services, from the denominator. In addition, CMS is willing to address this issue again in the future as the core measure set is implemented across all States to determine if its use will be viable for EPSDT reporting.

**Line 1.c. Total Individuals Eligible for EPSDT under a CHIP Medicaid Expansion Program**

One commenter indicated that the instructions for this line limit the number of children to be reported to those only eligible for at least 90 continuous days (line 1.b.) and thus those children would not be counted the same as other children meeting this criterion.

**CMS Response**

This line of data is for informational purposes only and should include any child from line 1.b enrolled in a CHIP Medicaid Expansion program as of September 30. This will be consistent with all other data used on the form other than the data reported in line 1.a.

**Line 3.b Average Period of Eligibility**

Two commenters indicated that using line 1.b., the children who are eligible for 90 continuous days in determining the average period of eligibility makes this line of data invalid.

**CMS Response**

CMS is revising line 3.a to instruct States to enter the total months of eligibility for individuals in each age group on line 1.b, not 1.a, so that the average period of eligibility is only for those children eligible for 90 continuous days. This will ensure consistency with the rest of the calculations on the form.

**Line 6 – Total Screens Received**

One commenter indicated that CMS’ use of the word “may” indicates that States can make alterations to the set of procedure codes used to identify services. CMS should require that States use the standardized set of codes.

**CMS Response**

CMS uses the word “may” in the instructions to allow for States that may use multiple ways of capturing data the flexibility to use that data. The codes included in the instructions are noted as “proxy” codes. While States are no longer allowed to use State-only codes to report services, there are States that use various sources to ensure that a complete child health screening is captured. For example, in some States a child may receive an immunization or lead screening from a health department. The State can combined that information with the well-child screening visit to ensure all age appropriate elements of the screening have been provided. Some States may also use encounter data or data from chart reviews to report comprehensive data.

**Note preceding Line 12a**

Two commenters indicated the Notes for reporting lines 12.a – 12.g was confusing and should be moved. Also both commented that it was not clear whether the eligibles to be counted are from line 1.a or line 1.b.

**CMS Response**

CMS will move the information in the Note to better clarify that the information pertains to lines 12.a – 12.g. CMS will also clarify that the individuals to be counted are from line 1.b.

**Data to report services of a dental hygienist**

One commenter indicated that with respect to preventive services reported on lines 12.b vs. line 12.f, it is not always possible for States to determine whether a service provided by a dental hygienist was provided under the supervision of a dentist or not. For example, a particular State allows dental hygienists to provide preventive services in public health settings without a dentist supervision, but there would be no way to know if claims for those services were provided under dentist supervision or not.

**CMS Response**

CMS is making no changes based on this comment. CMS has discussed this issue several times with the OTAG members. Under Federal Medicaid regulations at 42 CFR 440.100, services provided by dental hygienists or any other dental extender that are provided under the supervision of a dentist, are billed by the dentist and counted on line 12.b as dental services. It does not matter who provided the service; what matters is who is ultimately responsible for the service and bills for it. Services to be included on line 12.f are services provided and billed by non-dentists. States who reimburse independently practicing dental hygienists under 42 CFR 440.60, other licensed practitioners, would report those services on lie 12.f, not line 12.b. If a dental hygienist is not practicing under the supervision of a dentist or is not allowed under the State’s Medicaid plan to bill independently for services, Medicaid should not be reimbursing for those services as they do not meet the Federal Medicaid requirements.

**Line 12.a through 12.g**

Two commenters indicated that it was unclear whether the unduplicated number of children reported on lines 12.a – 12.g is a subset of line 1a or line 1b.

**CMS Response**

CMS will update the Note in the instructions to clarify that all data reported on line 12 should be based using the eligibles noted in line 1.b, those eligible for 90 continuous days.

**Line 12.f – Total Eligibles Receiving Oral Health Services Provided by a Non-Dentist Provider**

One commenter believes that the data for oral health services provided by a non-dentist should not be combined into a sum of dental services. While these services may be somewhat effective in addressing specific oral health needs, they do not replace the need for comprehensive oral health services that are provided by dental professionals, and instead, may reduce a parent’s understanding of the need to also seek comprehensive oral health care through a dental professional. The commenter also indicates that if CMS is determined to include non-dentist services, they should be reportedly separately, with a footnote as to what types of providers can provide what specific services under the State’s Medicaid or CHIP program.

**CMS Response**

It appears the commenter may have misread the instructions for line 12.f or is referring to line 12.g. The instructions for line 12.f indicate that the data to be reported is only for services provided by non-dentists, as recommended in the comment. CMS does not feel there is a need to clarify this further. Also we do not intend to request that each State inform us of the type of providers counted on line 12.f particularly on the form itself. As we indicate in the instructions, due to State Practice Act variations as well as State Medicaid Agency coverage policies, not all States may have data to report on line 12.f if they do not allow non-dentists to furnish and bill for oral health services. There is no requirement for States to do so. There will be no consequences if a State reports “0” on line 12.f.

Line 12.g is intended to capture a total number of eligibles receiving any dental or oral health service. This is an informational number and not used in any specific calculations. It is intended to give CMS and other interest parties an indication of total dental/oral health services being provided to eligible children.