August 1, 2007

Amanda Stangis
Director of Programs
California Primary Care Association
1215 K Street, Suite 700
Sacramento, CA 95814

Re: Request for Comments,
Agency Information Collection

Dear Ms. Stangis;

This letter is in response to your request for comments on HRSA's 60-day request for comments placed in the Federal Register on Friday, April 13, 2007 at page 18661 on the 2008 Uniforms Data System data collection.

Your comments and our responses are below:

1. Inadequacy of the Announcement.
Comment : The appropriately brief announcement indicated that detailed information could be obtained by contacting the HRSA Reports Clearance Officer which we did. We were then directed to a web site maintained by the Bureau of Primary Health Care and a document called the 2008 UDS Manual. The document, however, was *not* the manual. Instead, it was copies of the tables and a statement of which tables would be changed. *No instructions, which normally take up nearly 100 pages in the UDS Manual, were included.* Since the level of burden and the quality, utility and clarity of the information to be collected is totally dependent on these instructions, our comments are, of necessity, tentative. **We formally request that the announcement be reissued with the full information included so that it would be possible to fully evaluate impact, cost, burden, and accuracy.**

Response: The required FR notices for agency information collection activities typically do not contain the instruments, instructions, or other supplementary materials associated with the data collection activity. Due to size limitations, materials are provided based upon request. A total of two calls from two different organizations were made to the HRSA Reports Clearance Office requesting materials as a result of the 60 day FRN. The RCO did indeed direct callers to a web site for materials. The web site mentioned above provided the sections of the 2008 UDS which contained the proposed revisions. The sections with the proposed revisions also contained information describing the measures and definitions for the table requirements for the new measures in those sections. The instruction manual for the sections of the proposed UDS that were <u>not</u> revised was also available on the HRSA web site, and the caller was informed of this information. The sections of the Manual that were not changed were available in the Manual currently in use and up on the web and available for review. The RCO specifically requested that the caller

inform the office of <u>any</u> other materials that were needed for review, and to report any issues or problems if the materials on the web were not sufficient, in order to ensure that all requested materials were made available for comment. No additional calls were received. It is the intent of the HRSA RCO to ensure that there is <u>complete transparency</u> in all proposed agency information collection activities.

2. Enhancing the quality, utility, and clarity of the information to be collected:
2.1. CPCA's ongoing need for data identified for elimination.
Comment: As a HRSA-BPHC funded Primary Care Association, it is our responsibility to make known the quality and quantity of services rendered to the medically uninsured and underinsured, and to advocate for these populations. To do so, it is critical that we have information about both the CHCs serving the population and their patients. This has traditionally been made available to us through UDS data including information on Tables 2, 6, and 7 which are slated for partial or total elimination.

• Table 2: Services Provided. Table 2 provides a listing of some 77 services which are of value to the target population. Each responding health center checks whether or not they provide the service and how it is provided. Our CHC representatives tell us that this table takes less than an hour to complete initially and a fraction of that time to revise annually. No burden is relieved by its elimination. On the other hand, the information contained in this table permits CPCA to describe the CHCs in California. We proudly point, for example, to the fact that 100% of CHC grantees in California provide or provide for diagnostic lab, diagnostic x-ray, family planning, and HIV testing and counseling. Similarly, 100% provide gynecological care and prenatal care; 99% provide dental care and mental health treatment/counseling, and so on. To lose this valuable tool will only make our job of advocating for CHCs in California that much harder.

<u>Response:</u> The proposed changes in data collection are intended to increase HRSA/BPHC efficiencies in data acquisition and management, not to restrict or deny access to data needed by organizations explicitly working with HRSA and in the interest of the health center program.

Data equivalent to the sites and services information currently in the UDS will be collected through grant applications and stored electronically. This information will be made available to partners and stakeholders in periodic reports. Also, information required by partner organizations to perform functions under contractual or grant agreements with BPHC will be made available to them.

• Table 6: Selected Diagnoses and Services. Table 6 – a source of information on the patients we serve and the services we provide to them – would be totally eliminated. When we talk about the patients we serve, it is extraordinarily important to be able to say that, for example, in 2005 422,675 patients were served who had a primary diagnosis of diabetes or that 376,602 had a primary diagnosis of hypertension. CHCs do the preventive health care for the community (over 500,000 children received well child care) but they also treat the chronically

ill patients for whom treatment is essential. This tool is similarly valuable and important to our function.

Response: In response to grantee and partner requests, the "old" Table 6 will be kept and relabeled Table 6A. The "new" Table 6, Quality of Care Indicators, also will be kept and relabeled Table 6B. In order not to increase further the grantee reporting burden, only primary diagnosis will be collected on the Table 6A

• Table 7: Perinatal Profile. Liens 3 through 8 would be eliminated (among others.) The information showing that health centers delivered 32,416 women in 2005 should be retained and is meaningful. But equally meaningful in telling the story of the health centers is the fact that 17.2% of those mothers were teenagers, and that 280 were less than 15 years old. This detail would be lost. We also would lose the fact that during that year nearly twice as many women (62,190) were provided with perinatal care. We need this information as well.

Response: Prenatal age categories will be kept in the new Table 6. The number of deliveries for prenatal care patients will continue to be reported in Table 7.

2.2. Grantees may well be unfairly evaluated with the measures proposed and HRSA inappropriately found to fail.

Comment : New data are to be collected in tables numbered 6 and 7 and designed to measure "Quality of Care" and "Health Outcomes and Disparities." Because the instructions are not provided, we remain unclear about what will be measured, but the potential for misrepresentation and damage is great. (The burden involved will be discussed later.)

• Table 6: Childhood Immunization Rate. Table 2 asks as seemingly simple question: What proportion of the children served by the CHC were fully immunized on their second birthday? But the devil lies in the details which are omitted from the Federal Register notice and the accompanying materials. California's CHCs provide ongoing care for hundreds of thousands of children, including roughly 50,000 who would have turned two in 2005. Many, if not most, are our regular patients. But a large (though unknown) number may have come in once for an acute illness because they could not get to their regular doctor, and then never again. Another 40,000 were seen in their first year and never again. One group of six clinics responded in detail as follows:

"Our consortia recently wrote a federal grant in which we were asked to include the immunization data for 2-year-olds in the same format as the new UDS reports. It was impossible for any of our six clinic members to get accurate data on this, with the significant exception of one of our clinics who participated in the Statewide Immunization Registry. One of our clinics did pull charts in order to figure out her vaccine rate and found that only 2 out of 38 2-year-olds APPEARED to be up to date on their vaccines. The problem is that parents bring their child to the local pediatric group for well-child visits, maybe go to the Dept. of Public Health once in a while for a vaccine, and end up going to the clinic when their child is sick for a single or two appointments in the span of a year. So, even though the child is counted as a clinic patient, the

child is really getting their immunizations at another location. So, clinic records are either incomplete in terms of vaccinations, or are missing altogether (because the kid came in for poison oak or an ear infection, and vaccine information wasn't collected and/or documented.) Thus, it generates artificially low vaccination rates for our clinic patients."

California CHCs would limit this variable to those children who were seen during the reporting year and who had been seen at least three times in the two years prior to their second birthday. If this is not done, the CHCs and HRSA will appear negligent.

Response: For the 5 new clinical indicators, the denominator for the proposed measures is identified by the number of patients within the age/gender category or by those diagnosed with the condition, as identified by ICD9 codes. Similarly, the numerator is specified for the measurement year and/or years prior to the measurement year or by a certain age, consistent with specifications of national organizations and HRSA.

HRSA recognizes that in certain circumstances a minimum number of visits would show better performance using the clinical measures. However, it is considered important that performance be depicted accurately for all health center patients. In the future, HRSA will work with grantees and seek advice from expert organizations to refine definitions and increase specificity.

- Table 6: Childhood Lead Test. A second question is asked about lead testing: What proportion of children served by the CHC received testing for elevated lead levels by the age of three. This question no doubt seems reasonable to people in Washington D.C. where the old lead paint in apartments where the indigent live often provides a source of lead poisoning to children. This is so much not the case in the west that, at least in California, our clinicians rarely conduct lead screening tests. Instead a risk assessment is routinely done and, if exposure is indicated, then, and only then, is a test ordered.

But even if the language were changed to risk assessment or testing, we are still facing the problem of who we would look at. In California, a quarter of a million children were under the age of three at some point in 2005. Of these, tens of thousands were never in the practice long enough to be tested and many – probably in excess of 50,000, had not been seen for over a year.

California CHCs would limit this variable to those children who were seen during the reporting year, who had been seen at least three times in a period of not less than six months nor more than two years, and would count *in compliance* children who had a risk assessment as well as those who had a blood test. If this is not done, the CHCs and HRSA will appear negligent.

Response:

Blood test screening can help detect lead poisoning that negatively impacts on childhood development. In recognition of the vulnerability of children served by health centers to

elevated blood levels, Congress mandated that HRSA report annually on blood lead level tests for health center children. (Public Law 106-310, Title XXV of the Children's Health Act of 2000, Sec. 2503 (b)) As a consequence, health center grantees will be asked to report lead test screenings for their patients, whether the screenings occur on site or at the local health department.

4. Burden statement.
Comment: The current UDS carries with it a stated burden of 24 hours. The Federal Register suggests it would increase to 30 hours or an additional six hours. Removal of Table 2 would not have reduced the burden at all, but removal of table 6 and part of 7 would have removed some portion. Grantees suggest that, compared to the financial tables, the amount would have been minimal. Most have practice management systems which provide the numbers which are then just copied into the form. It would appear that, at most, the estimated burden of adding the clinical tables is one person day or eight hours. Grantees representing roughly 10% of CPCA's BPHC funded members responded to a request to estimate the burden involved in responding to the clinical items. The four which were most clearly quantified are summarized here. We assume that the five new measures will each require 70 charts to be pulled, or a total of 350 charts:

- Agency #1. Immunization data are available from a registry. The time to collect was thought to be relatively minimal. To collect data for lead test screening and Pap tests would take 15 hours each. To collect hypertension and A1c data would take 23 hours each or a total of 76 additional hours.
- Agency #2. Chart reviews would take approximately 20 minutes per chart for each of the variables or a total of (350 * 20 / 60) 116 additional hours.
- Agency #3. Chart reviews would take an average of 17 minutes per chart, however the time they felt it would take to find and replace the charts was probably excessive. Cutting this time in half brings us to 10 minutes per chart or (350 * 10 / 60) 58 hours.
- Agency #4. Chart reviews took as much as 20 minutes at first, but settled down to 10 minutes per chart. Using 10 minutes we again get 58 hours.

What is most remarkable is the relative consistency of the estimates, with three of them in the 58 to 76 hour range and one at 116. What is most notable is that none of them come even close to what we would consider to be the roughly eight hour HRSA estimate of added burden. The burden statement seems to be off by an order of magnitude or more! The overall burden would appear to increased by as much as 300% with the addition of these elements. We understand that a pretest was done to assess the burden but that it was completed after the April 6 drafting of the Federal Register notice.

Response: It is correct the test burden calculations were completed after the April 13, 2007 Federal Register Notice (FRN). The test included health centers across the nation of varied sizes, patient characteristics and population sizes. The test sites conducted systematic sample chart reviews based on the patient population of the specific condition. Unlike the Agency #1 through #4 of the CPCA test, sample sizes ranged from 21 charts (or all charts if site had less than 30 patients) up to a maximum of 67 charts. The test burden calculations take into account these

differing reporting characteristics and patient population sizes that exist across the health center program. Based on these factors, the burden calculations for collecting and reporting the new clinical measures have resulted in an overall increase in the burden from that estimated in the FRN. Taking into account burden reductions from the elimination of current data elements, the estimated burden has increased from 30 hours universal reports and 18 hours grant reports in the April 13, 2007 FRN to the current 54 hours universal reports and 44 hours grant reports.