STATUS OF ADMINISTRATIVE AND REGULATORY HEALTH POLICY ISSUES AFFECTING HEALTH CENTERS

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NACHC's "ACCESS for ALL America" plan projects serving an additional 15 million underserved people through health center programs by 2015. To strengthen existing, newly funded and expanded health centers and to continue to expand access to primary care through the health center programs, it is critical that the regulatory and policy environment impacting centers enable rather than impede achievement of health center goals. Below is a brief summary of the current status of select regulatory health policy issues monitored by NACHC staff and legal counsel on behalf of health centers.

HRSA-RELATED POLICIES AND REGULATIONS

HEALTH CENTER EXPANSION AND DEVELOPMENT INITIATIVE: SUCCESSES AND CHALLENGES

Completion of PI-1 and Progress on PI-2: On a celebratory note, a HHS press release issued on December 5, 2007 announced the fulfillment of a key goal of the President's 2001 Health Center Expansion Initiative (PI-1) – the addition of 1200 new or expanded health center sites; and provision of services to over 4.7 million additional health center patients. HHS noted that, based on the success of the first expansion initiative, in 2005 the Administration had launched the High Poverty Counties Initiative (PI-2), which resulted in $40 million in funding in 2007 for 80 new health center sites.

NACHC also notes that the vigorous implementation of the health center growth initiatives is indicative of significant unmet need and pent up demand in local communities for accessible and affordable primary care. It is also a tribute to the hard work, energy and practical skills of the health center movement (health centers, primary care associations (PCAs), Primary Care Offices (PCOs), colleagues, and advocates throughout the country) - as well as HRSA- in productively turning these funding opportunities into sources of ongoing health care for people in need in 1200 more local communities.

Final FY2008 Appropriations Decisions Slow Growth Despite High Demand: Despite initial successes, given the twists and turns of the Congressional budget and appropriations process for

FY 2008, high federal deficits, and the competing demands of war and a slowing economy, the FY 2008 health center appropriation increase turned out to be less than had been requested by NACHC and planned by HRSA. However, the health centers program still received a $112 million increase in the appropriation. Because of a 1.747% across the board rescission applied to individual health center grantees; this resulted in $77 million net funding increase. Many other federal discretionary health programs (including the National Health Service Corps and the Maternal and Child Health Block Grant) received cuts, were flat funded, or got very minimal increases. As a result, HRSA has revised its planned expansion funding goals for the year. HRSA intends to allocate the available new FY 2008 expansion funds as follows:

- New Access Points (NAP): $25 million to support 42 awards (down from $46 million for 75 awards as projected originally last fall). Approximately 260 applications were submitted.
- Expanded Medical Capacity (EMC): $10 million to support 20 awards (down from $50 million and 85 awards). Approximately 225 applications were submitted.
- Service Expansion SE): $30 million to support 160 awards – 60 Mental Health/Substance Abuse, 60 Oral Health and 40 Pharmacy (no change from original projections). Approximately 203 MH/SA applications; 277 Oral Health applications; and 100 Pharmacy applications were submitted.

It should be noted that **approximately 1065 applications were submitted to compete for only 222 NAP, EMC, and SE awards,** indicating a high level of interest and demand from local communities and health centers for expanded services and sites.

HRSA is also expected to issue guidance for health center planning grants shortly for up to $2 million for 25 awards of up to $80,000 each to eligible organizations (and to award $40 million in base adjustments for all eligible grantees).

FY2009 President's Budget Request Falls Short of NACHC Goals: The President's Budget Request for FY 2009 contains a $26.8 million increase for New Access Points and Planning Grants in High Poverty Areas (not Counties), well below NACHC's FY 2009 request for health centers. NACHC immediately issued a statement registering disappointment with the Budget Request and noting that a recent report with the Robert Graham Center found that 56 million people, nearly 1 in 5, lack access to basic medical care and a source for primary health care. NACHC indicated that the health center movement will look beyond the President's budget to the future and vigorously embrace their ACCESS for ALL America plan designed to significantly reduce the ranks of people without a health care home by serving a total of 30 million patients by 2015.

FY2008 Guidance and Timing Concerns: On the implementation side for FY 2008 expansion funding, many applicants are concerned about the lead time from application to award announcements and start dates. Applicants will have to wait at least six months before they know whether they are funded. Some centers may have to choose between either waiting for months or moving ahead at their own risk to initiate needed services without knowing whether they will have federal support for doing so. NACHC is working with BPHC to try to understand why the process for reviewing and announcing awards cannot be more efficient. In a related area, some applicants continue to complain about inconsistent and erroneous comments and scores from the Objective Review Committees. NACHC is collecting specific examples and will be submitting a memo to the Director of the Office of Independent Review requesting review of the process.

It also should be noted that the original expansion guidance contained numerous unintended inconsistencies, obstacles and restrictions that could have significantly reduced the pool of eligible applicants; however, when NACHC and others pointed out these problems, BPHC was responsive to input from the field. They revised and clarified the eligibility guidelines for all three initiatives to include greater flexibility and the opportunity to build on existing services.

Certification of FQHC Look-Alikes (FQHCLA): As of January 2008, there were 94 designated FQHC Look-Alikes. Although two new centers were designated this past fall, this is a net reduction of seven, all of which converted to grantees after last year's NAP opportunities.

Indications are that the much-anticipated new FQHCLA guidance will be issued in the late spring to summer. This guidance is expected to add health and business plan requirements.

Service Area Competition (SAC) and Budget Period Renewals: The FY09 SAC (competing project period) guidance for project periods with start dates November 1, 2008 through June 1, 2009 are now posted on www.hrsa.gov/grants. Centers are required to use the guidance appropriate to their application deadline, per the following chart:

Project Period Start Date	HRSA Announcement Number	Grants.gov Application Deadline	Electronic Hand Books (EHB) Deadline
November 1, 2008	HRSA 09-095	April 7, 2008 at 8:00 PM ET	April 21, 2008 at 5:00 PM ET
December 1, 2008			
January 1, 2009	HRSA 09-096	June 2, 2008 at 8:00 PM ET	June 16, 2008 at 5:00 PM ET
February 1, 2009			
March 1, 2009	HRSA 09-097	July 28, 2008 at 8:00 PM ET	August 11, 2008 at 5:00 PM ET
April 1, 2009	HRSA 09-098	August 29, 2008 at 8:00 PM ET	September 15, 2008 at 5:00 PM ET
May 1, 2009			
June 1, 2009			

The new SAC guidance includes several important changes, including: required data points for the Needs Criterion; required performance measures for both the Health and Business Plans; a new format for Health and Business Plans; several changed forms and content requirements; and a 2-part electronic submission process. **Please be sure to review the changes noted on the first page of the guidance.** Information about the guidance and application process can be found on the HRSA website at www.hrsa.gov/grants/technicalassistance;sac.htm. A replay of the 3/5/08 BPHC TA conference call is available at 1-800-204-3093 through September 14, 2008. BPHC will be holding an additional TA call in the next 2 weeks to review the changed Health and Business Plans. NACHC will post call-in information as soon as it is available.

Beginning in FY 2009 the applications will include a set of performance measures that all applicants must report on in their health and business plans beginning in FY 09 and "where possible" (BPHC language) include baseline data in the initial report. These are:

- Health Plan measures: Diabetes, Hypertension, Childhood Lead Exposure, Childhood Immunizations, Pap Tests, 1st Trimester Entry into Prenatal Care and Low Birth Weight.

- Business Plan measures: Total Cost per Patient, Medical Cost per Medical Encounter (data from UDS) Change in Net Assets to Expense Ratio, Working Capital to Monthly Expense Ratio, and Long Term Debt to Equity Ratio (data from annual audit).
- One Behavioral Health (e.g. Mental Health or Substance Abuse) and one Oral Health performance measure of their choice in the Health Care Plan.

Grantees will be required to report quantitative and qualitative progress in annual budget period renewals on all of theses measures. While NACHC would agree that these indicators are among basic measures of providing quality health care and operating a cost efficient and stable organization, they are a continuation of an increase in prescribed requirements being experienced by health centers. There is some push back from centers, indicating that center effectiveness has always been a reflection of their abilities to respond to the unique needs of local communities. NACHC will continue to monitor this to ensure that health centers have the flexibility they need to meet the challenges of their populations. For more information, contact PByrnes@nachc.com

FY 2008 BASE GRANT ADJUSTMENTS

HRSA announced last week in its PAL 2008-03 letter that it will award $39.4 million to existing health centers for base adjustments in FY 2008. Noting that FY 2008 appropriations bill included an across the board 1.747 percent reduction to the Health Centers program, HRSA said that the base grant adjustments would offset the across-the-board reduction, with each health center receiving both a 2 percent increase and a 1.747 percent reduction to its FY 2008 target funding level, resulting in a net base adjustment increase of .253 percent. HRSA added that it will use $4.4 million of the $39.4 million to make an additional adjustment of 1.497 percent to health centers whose 2006 patient population was at least 70% uninsured, or whose uninsured patient load grew by at least 50% between 2004 and 2006, according to its UDS reports.

NEW NOTICE OF PROPOSED RULE –MAKING (NPRM) ON DESIGNATION OF MEDICALLY UNDERSERVED POPULATIONS (MUPs) AND HEALTH PROFESSIONAL SHORTAGE AREAS (HPSAs) PUBLISHED (73 Fed. Reg. 11232, et seq (February 29, 2008)

Proposed Shortage Designation Regulations Revise & Consolidate MUP and HPSA Process and Criteria: After taking nearly a decade to think about the new proposed regulations, HRSA has published a new set of proposed rules for designation of MUPs and HPSAs, with a very short deadline for public comments of April 29, 2008. These proposed regulations will have implications for every health center since all MUPs and HPSAs will be reevaluated in phases using the new criteria. The new proposed regulations would consolidate the criteria and processes for shortage designations, which are used today to determine eligibility for many federal programs, including Section 330 Health Center grants, National Health Service Corps (NHSC) providers, the issuance of J-1 visa waivers, the Medicare and Medicaid FQHC and RHC payment systems, and even the special 10 percent “bump” in Medicare payments that private physicians can get if they practice in a HPSA.

3000 to 1 Population to Provider Ratio to be Used: The proposed rule describes a revised methodology – developed by a research team at the University of North Carolina’s Cecil G Sheps Center in consultation with HRSA staff and a group of state partners – which combines indicators of diminished access to health care services, shortages of health professionals, and reduced health status. In the new proposed rule, HRSA apparently has insisted on maintaining its 30- year old

3000-to-1 FTE threshold for designation of MUPs/HPSAs, even though (as it concedes in the Preamble to the regs) – that ratio is "twice the normal load for a busy primary care physician."

Public comments are invited by April 29, 2009, a very tight deadline given the analysis required. The new proposed regulations will not take effect until after the public comment period is over, and after the House Energy & Commerce Committee and the Senate HELP Committee have both reviewed and commented on it – and in no case before six months after HRSA's delivery of the regs to the Congressional Committees noted above, in accordance with the 2002 Health Centers reauthorization law.

Initial Review Shows Disproportionate Negative Impact on Urban/Metro MUPs/HPSAs: Preliminary review of the proposed rules reveals that – in the process of attempting to correct a substantial "anti-rural" impact that the rules originally proposed in 1998 had been accused of – the new rules appear to trigger a disproportionate "anti-urban" impact this time around; while 98% of rural and 99% of current frontier MUP/HPSA designations would be retained, only 82% of current urban designations would be continued. For health centers, HRSA notes that 94% of those with whole county MUAs would retain their designations, while 85% of those with part county MUA/MUPs and only 76% of those with population based MUPs would retain their designations. In all, an estimated 176 health center sites could potentially face loss of geographic or population-based designations unless they qualify under a new "safety net facility" designation that NACHC had advocated for in review and comment on the first proposed regulations. HRSA has not provided information as to which specific MUA/Ps would be affected that have health center grantees, making it more difficult for local communities to conduct their reviews.

"Safety Net Facility Designation Based on Facility's User Profile as Final "Fallback" Provision: This provision would enable a facility to qualify as a HPSA and a MUP based on the characteristics of the facility's actual patient population served. The rule proposes that if at least a certain percentage of a facility's actual patient population served is either Medicaid or uninsured (40% for metro, 30% for rural and 20% for frontier) the facility can qualify as a HPSA and MUP. However, given the wording of the proposed rule, it is not clear whether the whole facility and its entire 330 scope of project would qualify or just the Medicaid and uninsured populations of the facility or a single site/location of the health center organization.

NACHC Urges Centers & PCAs to Request Additional Ninety Day Extension of Time to Submit Comments: Given the importance of the proposed rule, all health centers are urged to work with the PCAs and PCOs in analyzing the specific impact of the regulations on health centers in their states, to stay in touch with NACHC as we develop comments, and to submit your own comments. NACHC has requested an additional ninety day extension of time to conduct such analyses and prepare meaningful comments due to the complexity of the proposed rule. Centers and PCAs are encouraged to also request an extension of time to prepare comments.

HRSA SCOPE OF FEDERAL PROJECT POLICY DEVELOPMENTS

Important BPHC Scope of Federal Project Policy Information Notices Issued and Still Pending: The BPHC continues to reassess and clarify its policies for all-important "scope of project" for health centers. This fall, NACHC submitted comments on three draft BPHC PINs, including on a basic scope of project policy PIN, a specialty services PIN, and a PIN on expanding services from one target population to another. The BPHC is still working on a first draft of a PIN on provision of health center services in institutional settings (such as jails and nursing homes) which has not yet been released for review and comment. They are also working on issuing the specialty and target population PINs in final form. However, they have released in final form PIN 2008-01: Defining Scope of Project and Policy for Requesting Changes. This is the "basic" BPHC scope PIN, and should be reviewed and understood by all health center managers. Even though the BPHC didn't agree with every suggestion NACHC made in its comments, the new Basic Scope PIN represents an update and improvement over previous, outdated policies. There continues to be concern in the field about whether the specialty and institutional care PINs will permit centers the flexibility they need to operate in today's changing health care environments. Contact Pam Byrnes at PByrnes@nachc.com for more information.

FEDERAL TORT CLAIMS ACT ISSUES

Federal Tort Claims Act (FTCA) Issues: Recent actions by HRSA and the HHS Claims Office have resulted in possible new "gaps" in FTCA coverage (not previously identified by the BPHC or others) that could have implications for health centers. In one recent case, HHS declined to cover a health center and its provider (a nurse-midwife) who assisted other community providers in an inpatient setting with delivery of a non-health center patient, an unwritten reciprocal practice among providers at that community hospital (i.e. other providers also assist health center providers if needed). While the details of the specific case are under appeal, the decision has set off concerns among health centers and their clinicians about whether or not health centers can rely upon FTCA coverage being there when they need it, i.e. when a claim is filed. NACHC has written the BPHC urging them to reconsider this decision and issue a "blanket particularized determination" indicating that such reciprocal assistance arrangements that are integral to the practice of medicine are coverable under FTCA. It appears that HHS is taking an increasingly strict constructionist view of FTCA coverage, and rather than applying the broad principles of FTCA to individual scenarios to determine if a case is within 330 scope of project and the rules of FTCA or not, HHS appears to want to see explicit authorization that a specific given arrangement is coverable. Since it is impossible to create an exhaustive list of every single coverable activity conducted in the practice of medicine, some centers either already have or plan to purchase private gap or wraparound insurance to protect themselves and their providers from finding themselves "without coverage" they thought they had under FTCA. Since gap policies can cost almost as much as full malpractice coverage, a stampede to purchase gap policies could nullify the whole cost-savings purpose of securing FTCA for centers in the first place.

There are also other concerns about FTCA that have arisen in the field, including failure of the federal government to routinely inform providers and centers when a settlement is made in a case and the names of the providers are reported to the National Practitioner Data Bank. Health center providers should not have to discover their names in the Data Bank by accident, without any prior knowledge. NACHC will be discussing these and other issues with the BPHC at a variety of levels. NACHC has also asked BPHC to clarify in writing whether or under what conditions prescriptions written by providers for non-health center patient "partners" of health center patients with sexually transmitted diseases are covered under FTCA.

HRSA DATA, TECHNOLOGY, AND REPORTING DEVELOPMENTS

HRSA Data Strategy: HRSA is rapidly moving forward with migrating toward greater use of on-line technologies for collecting grantee data. The HRSA Electronic Handbook (EHB) is being upgraded to facilitate electronic data collection and changes for scope related issues; uniform data system reporting; and funding requests to include service area competition, budget period renewals, new access points, and expanded medical capacity. HRSA has engaged grantees to provide Base Scope Verification (BSV) data for services and sites, convened User Acceptance Testing focus groups to streamline the electronic application submission process, and data strategy focus groups to discuss HRSA data collection strategies for all HRSA grantees. The process is expected to be completed by January, 2009. HRSA also expects that by spring 2008 change in scope of project forms will be completed and submitted on-line through EHB. Contact John Ruiz @ jruiz@nachc.com for more information.

Base Scope Verification (BSV): Pursuant to PIN 2008-01 (Defining Scope of Project and Policy for Requesting Changes) and the migration toward greater use of on-line technologies for collecting grantee data, BPHC grantees have been directed to update scope information for their organizations in the HRSA electronic handbook (EHB) by February 29, 2008. The process includes verification and update of the grantee organization profile, services provided, and site information. The process also includes providing justification for the non-provision of required services and provision of additional services. Each grantee must complete the BSV process by February 29, 2008 in order to submit any FY 2009 grant applications for continuing and/or new funding, including annual renewal applications (Service Area Competition and Budget Period Renewal). Grantees have been advised that failure to provide the requested information may result in their inability to apply for future funding. NACHC has received feedback from some grantees of technical issues in the electronic process. To assist grantees in the process, HRSA has provided technical assistance web-casts, set up a systems help website at http://www.bphc.hrsa.gov/systemhelp/ and a BPHC BSV help line at 301-443-7356. For more information, contact John Ruiz @jruiz@nachc.com

Uniform Data Systems (UDS): HRSA has announced the availability of the UDS manual for CY 2008 reporting. The manual includes elimination of tables and inclusion of clinical performance measures (health indicator outcomes) discussed extensively in the previous year. Specifically, table 1, table 2, Table 8b, table 9b, and table 9c have been deleted. Table 7 has changed to provide health outcomes and disparities information. The manual is available on the HRSA website at http://www.bphc.hrsa.gov/uds/2008manual/default.htm. For more information, contact John Ruiz at Jruiz@nachc.com

HRSA Health Information Technology (HIT) Strategy. HRSA has published their response to comments solicited in the Federal Register Notice (FRN) published on September 19, 2006 regarding strategies to support health information technology among HRSA's safety net providers. The FRN proposed strategies to support HIT among safety net providers, and requested comments on HIT topic areas addressing quality improvement, collaboration, general network related issues, specific health center controlled networks related issues, sustainability and building HIT capacity. The HRSA response can be found in the Federal Register: January 25, 2008 (Volume 73, Number 17)] [Page 4584-4592] at http://a257.g.akamaitech.net/7/257/2422/01jan20081800/edocket.access.gpo.gov/2008/E8-1301.htm. Contact Mike Lardiere for more information.

HRSA EMERGENCY MANAGEMENT DEVELOPMENTS

In late August 2007, HRSA released long-anticipated Policy Information Notices (PINs) related to emergency management. The two PINs, 2007-15, Health Center Emergency Management Program Expectations and 2007-16, Federal Tort Claims Act Coverage for Health Center Program Grantees Responding to Emergencies, are both extensions of previous PINs and provide guidelines for centers as they engage in planning and preparedness activities.

PIN 2007-15 covers four main expectations related to developing an emergency management plan, collaborating with community partners, and communications during an emergency and financial/operational stability during and after a disaster. PIN 2007-16 provides more clarity around FTCA coverage in emergencies and describes FTCA coverage in three general situations:

a) establishing temporary sites within or adjacent to current health center service areas; b) establishing temporary sites outside of service area or in adjacent service areas; and c) assistance from non-impacted health centers. Health centers are strongly encouraged to review both PINs in detail and adjust emergency management plans as needed. Contact Mollie Melbourne at mmelbourne@nachc.com for more information.

MEDICAID & MEDICARE REGULATORY ISSUES

MEDICAID ISSUES

Medicaid Regulatory and Policy Issues*:* CMS' Restrictive Policies on SCHIP and Medicaid Expansion—On August 17, 2007, CMS Medicaid Director Dennis Smith issued a letter to State officials informing them that—in order to minimize the possibility of "crowd out"—a state will now have to assure CMS that it has enrolled at least 95 percent of the children in the State below 200 percent of the federal poverty level (FPL) who are eligible for either SCHIP or Medicaid before it can offer SCHIP coverage to those with income above 250% of the FPL. The letter provides that the state will also have to assure CMS that the number of children in the target population (above 250 % FPL) insured through a private employer has not decreased by more than two percentage points over the prior five year period, and that the state is current with all reporting requirements in SCHIP and Medicaid and that it reports data relating to crowd-out on a monthly basis. In short, CMS' policy makes it very difficult for a state to raise its SCHIP eligibility rules above 250% FPL without risking loss of federal SCHIP matching funds. Soon after issuing this letter, CMS, in September, 2007, denied approval of a New York plan that would have allowed families with incomes up to 400% FPL to participate in SCHIP. In December, CMS rejected an Ohio plan to expand Medicaid eligibility for children from 200% to 300% FPL—indicating that CMS may be applying more restrictive eligibility policies to Medicaid as well. A number of lawsuits by states (NY, IL, MD, WA and NJ) and beneficiaries have been filed against CMS challenging the legality of its SCHIP policy.

And a Host of Additional Proposed and Final Medicaid Regulations: CMS has been busy in the past eights months issuing a number of proposed and final rules, several of which are expected to substantially restrict Medicaid services for many beneficiaries and/or payments to providers. For example:

--On August 13, 2007, CMS published a notice of proposed rule making (NPRM) that restricts states from using Medicaid's rehabilitation service option to provide habilitation services to mentally retarded or other developmentally disabled patients or to pay for service that are an intrinsic element of another federal program. 72 Fed. Reg. 45201. CMS appears to view this proposed rule as a way to block states from utilizing rehabilitation services as a "catch-all' for a variety of services, but advocates for the disabled believe that the rules' prohibition of states using the rehabilitation option to provide "habilitation" services essentially eliminates a service that is critical to providing community-based care and will adversely impact patients' ability to be integrated into society and being able to maintain basic skills. The Medicare, Medicaid, and SCHIP Extension Act of 2007 (Pub No. 110-173), signed into law on December 29, 2007 prohibits CMS from implementing this proposed rule through June 30, 2007.

--CMS issued proposed regulations on September 28, 2007 that would narrow the regulatory definition of hospital outpatient services and puts restrictions on the calculation of upper payment limits (UPL) for outpatient hospital and clinic services provided by private providers. 72 Fed. Reg. 55158.

--CMS issued a final rule prohibiting federal Medicaid reimbursement for the costs of activities performed by school employees or other individuals other than the direct provision of medical services to eligible recipients, thereby eliminating federal financial participation (FFP) for the administrative activities of school-based personnel and transportation of children with disabilities to and from school. 72 Fed. Reg. 73635 (Dec. 28, 2007) the reduction of expenditures under this rule change has been estimated to be $635 million in FY 2009 and $3.6 billion over five years. However in the passage of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (Pub L No. 110-173), Congress prohibited HHS from implementing this rule through June 30, 2008.

In the past months NACHC has been a signatory to letters sent to key Congressmen and Senators requesting that Congress extend the two regulatory moratoria mentioned above, as well as a similar moratorium that currently prohibits CMS from implementing its finalized intergovernmental transfer (IGT) rules until May 25, 2008.

Medicaid Targeted Case Management Proposed Rule: CMS published an interim final rule with comment period for section 6052 of the Deficit Reduction Act of 2005 concerning case management and targeted care management (TCM) services. For purposes of the interim final rule, case management services are designed to assist Medicaid eligible individuals in accessing their required medical, social and educational services. These services range from individual assessment services to the development of a specific care plan to referral and monitoring services. Case management services are not medical services but services designed to help individuals transition into their communities.

The regulation substantially limits states' use of TCM for states. Under the new rule many services including certain child welfare and child protective services and the administration foster care services will no longer be reimbursed under Medicaid as TCM services. The rule also bans states from using TCM funding for activities necessary to administer a state Medicaid plan.

NACHC submitted comments on the interim final rule regarding a provision in the rule that requires state plans to provide that case management services will not duplicate payments made to public agencies or private entities under the State plan and other program authorities. NACHC's comments warned against CMS requiring the use of health center section 330 grant funds for the purposes of TCM services for Medicaid eligible beneficiaries. NACHC's comments clarified for CMS that section 330 grant funds are intended for uninsured patients not Medicaid eligible beneficiaries. Thus section 330 funds will be used to support TCM services for uninsured patients at or below 200% of the federal poverty level and should not be substituted for Medicaid funds to support TCM services for Medicaid beneficiaries.

Other Recent Medicaid Regulatory Activity by CMS Includes: In late August, CMS published a proposed rule that would allow state plans to provide for a non-emergency medical transportation brokerage program so that states could more cost-effectively provide such services to Medicaid recipients. 72 Fed. Reg. 48604 (August 24, 2007). The proposed rule states that these services can include wheelchair vans, taxis, stretcher cars, bus passes, and secured transportation containing an occupant protection system that addresses safety needs of disabled and special needs individuals. NACHC submitted comments on this proposed rule requesting that CMS make it clear that should a state decide to selectively contract with brokers to operate non-emergency services, the state would still be obligated to reimburse health centers that provide transportation to their patients.

On January 18, 2008, CMS issued a proposed rule that would allow states that provide personal care services through their state plan or a home and community-based waiver program to offer Medicaid beneficiaries who require such services to hire, direct, train, and fire their own personal care workers instead of working with personnel employed by an agency. 73 Fed. Reg. 3546. The proposed rule would allow qualified family members who are familiar with the individual needs of the beneficiary to be hired to perform personal assistance (not medical) services. If a state decides to adopt this self-directed personal assistance service, recipients could receive a cash allowance to hire workers to help with activities such as bathing, preparing meals, household chores and other related services that help an individual to live independently. Enrollment would be voluntary to the patient and the state must also provide traditional agency-delivered services if the beneficiary wishes to discontinue self-directed care. This rule puts in place a provision of the DRA.

Medicaid Section 1115 Waiver Activity: CMS continues to respond to States seeking to implement their versions of state health care reform through Section 1115 waivers. In December, CMS approved Indiana's "Healthy Indiana Plan" and in that same month Texas submitted to CMS a concept paper for a similar plan. Both plans would use uncompensated care hospital funds to provide private coverage to low-income uninsured adults. Also, in January 2008, CMS approved a state plan amendment (SPA) submitted by Missouri which constitutes Phase I of the State's "Insure Missouri" plan. Per the CMS approval, the State will be adding an alternative benefit package of services for custodial parents and caretaker relatives at least 19 years of age with income up to 100% FPL.

For a detailed review of the status of Medicaid Section 1115 waivers and approved SPAs being implemented under the expanded SPA flexibility provided under the DRA, see NACHC's *State Policy Report #19: 1115 Waiver and State Plan Amendments Matrix* (Dec., 2007). This document provides a general overview of individual state 1115 waivers and SPAs with a view toward provisions in those waivers/plans that directly impact FQHCs.

Tamper-Resistant Prescription Drug Pads: Beginning April 1, 2008 all written Medicaid prescriptions must be on a tamper-resistant prescription drug pad. The tamper-resistant prescription pad requirement applies to all outpatient drugs and over-the-counter drugs in states that reimburse for those items. To be considered tamper-resistant, the prescription pad must contain <u>at least one</u> of the following:

1. one or more industry-recognized features designed to ***prevent unauthorized copying*** of a completed or blank prescription form;
2. one or more industry-recognized features designed to ***prevent the erasure or modification*** of information written on the prescription by the prescriber;
3. one or more industry-recognized features designed to ***prevent the use of counterfeit prescription forms.***

CMS guidance on the provision does not further define the term "industry recognized" however the agency has identified nine states (California, Florida, Indiana, Kentucky, Maine, New Jersey, New York, Texas, and Wyoming) that currently have laws that are compliant with the provision and serve as examples for other states. Beginning October 1, 2008 <u>all three</u> requirements will be present on the prescription for purposes of Medicaid reimbursement. (Idaho's law is currently compliant through September 30, 2008 but not thereafter.)

The tamper-resistant prescription drug pad requirement does not apply to e-prescriptions transmitted to the pharmacy, prescriptions faxed to the pharmacy, or prescriptions communicated to the pharmacy by telephone by a prescriber. Thus health centers should avoid or minimize issuing written prescriptions to manage the expense and time necessary to maintain a consistent supply of the required pads.

States have the primary responsibility for enforcing the provision. Failure to enforce the law may result in the state's loss of Federal financial participation in the state's Medicaid program. States are not required to submit its enforcement plan to CMS.

Health centers should be aware that if a patient presents at a pharmacy with a non-compliant prescription on or after April 1, 2008, the pharmacy is required to refuse filing the prescription.

Click here to access the *CMS guidance Frequently Asked Questions Concerning the Tamper Resistant Pad Law*.

MEDICARE ISSUES

Update on Medicare Administrative Contracting Reform: NACHC continues to monitor the implementation of the new Medicare Administrative Contracting Reform. The Medicare Modernization Act (MMA) required the implementation of Medicare Administrative Contractors (MACs) responsible for processing Medicare claims based on 15 different regional jurisdictions. On April 1, 2007 the first MAC, Noridian Administrative Services (NAS), began processing Medicare claims for all health centers in Jurisdiction #3 (J3) which includes the states of Arizona, Montana, North Dakota, South Dakota, Utah and Wyoming. Since J3 began processing claims, CMS has awarded four new contracts. In August CMS awarded Jurisdiction 4 (J4) which includes the states of Colorado, New Mexico, Oklahoma, and Texas to Trailblazer Health Enterprises. In September 2007, Jurisdiction 5 (J5) including the states of Iowa, Kansas, Missouri, and Nebraska was awarded to Wisconsin Physicians Health Insurance Corporation. In October 2007, CMS awarded Jurisdiction 12 (J12) which includes Delaware, Maryland, New Jersey, Pennsylvania, and the District of Columbia to Highmark Medicare Services. Finally, CMS awarded Jurisdiction 1 (J1) which includes California, Hawaii, Nevada, American Samoa, Guam, and Northern Mariana Islands to Palmetto GBA.

Two of the four newly awarded jurisdictions (J1 and J12) are currently under protest by other competitors and as a result the transition and implementation of the new MACs will be delayed until the Government Accountability Office settles the dispute.

NACHC will continue to monitor Medicare Contracting Reform to keep health centers informed about changes in their Medicare fiscal intermediaries. As the transition dates and educational materials become available, NACHC will provide health centers with periodic updates. For more information on Medicare Contracting Reform please visit the CMS website at http://www.cms.hhs.gov/MedicareContractingReform/01_Overview.asp#TopOfPage.

Low-income Subsidy Proposed Rule*:* CMS announced a proposed rule designed to allow more Medicare beneficiaries with limited income to remain enrolled in their Medicare Part D prescription drug plan without having to pay a premium. Under the current *"de minimis"* demonstration project, CMS does not reassign full LIS beneficiaries enrolled in Part D plans that meet certain bidding requirements designed to keep costs low for the beneficiary. The new rule would eliminate that policy and Part D plans will keep their existing LIS beneficiaries if they meet certain requirements but will not be eligible for auto-enrolled people. Auto-enrollment will be available only to a small number of Part D plans with premiums that are equal to, or below, the LIS amount. CMS estimates the change will result in 200,000 fewer reassignments of Part D seniors. There is some indication that the rule does not drastically reduce the number of auto-assigned beneficiaries but is actually more of a cost-saving measure. NACHC will continue to work with other Medicare advocates to protect health center seniors from adverse regulatory proposals.

The rule will take effect in 2009. Click here to access the proposed rule.

DEVELOPMENTS IN FRAUD AND ABUSE LAW

OIG ISSUES LONG-AWAITED FINAL HEALTH CENTER SAFE HARBOR RULE

On October 4, 2007, the Office of Inspector General (OIG) at the Department of Health and Human Services (DHHS) issued the long-anticipated final rule establishing regulatory standards for the statutory health center safe harbor, which was enacted in December 2003 (72 *Fed. Reg.* 56632). The purpose of the safe harbor is to protect from prosecution under the federal anti-kickback law certain arrangements between health center grantees and providers/suppliers of goods, items, services, donations and loans that contribute to the health center's ability to maintain or increase the availability, or enhance the quality, of services provided to the health center's medically underserved patients. (NOTE: at this time, the safe harbor does not apply to FQHC look-alike entities)

In both the preamble to the final rule and the rule itself, the OIG favorably addressed many of the concerns raised by NACHC in its response to the 2005 proposed rule. In particular, the OIG modified and clarified provisions which NACHC believed would have a "chilling effect" on potential partners, including: (1) clarifying that the preamble reference to the OIG's efforts to monitor the parties to safe-harbored arrangements refers to its usual and customary oversight and not to a higher level of scrutiny; and (2) deleting the proposed requirement that the safe-harbored agreement comply with all relevant Section 330-related requirements.

The final rule includes eight requirements. In order for a health center arrangement to be protected by the safe harbor**, it must satisfy all eight requirements**.

1. ***Written Agreement***: The arrangement must be codified in a written agreement signed by the parties, which covers and specifies the amount of all goods, items, services, donations, loans, *etc.*, provided to the health center. The amount may be based on a fixed sum or a fixed percentage, or may be established by a fixed methodology. Further, there may be multiple agreements between the parties so long as the agreements reference each other or cross-reference a centrally located master list.

2. ***Scope of Goods and Services***: The goods, items, services, donations, loans, *etc.*, must be medical or clinical in nature or relate directly to any services (both clinical and administrative) provided under the health center's scope of project, including billing services, administrative and technology support, and enabling services.

3. ***Meaningful Contribution to Services Provided to Underserved Populations***: The health center must have a reasonable expectation that the arrangement will contribute meaningfully to services to the underserved. The health center must document its basis for the expectation prior to entering the arrangement, but does not have to establish uniform consistent measurement standards.

4. ***Re-evaluation of the Arrangement***: The health center must periodically (at least annually) re-evaluate the arrangement to ensure that it continues to meet the original expectation, and must document the re-evaluation at the time it is conducted.

5. ***Protection of Independent Professional Judgment***: The arrangement must not require or restrict the health center in making referrals it deems appropriate.

6. ***Provision of Services Regardless of Ability to Pay***: Any goods, items, and/or services offered to the health center (and, ultimately, to its patients) at no charge or at reduced rates must be furnished to all health center patients who clinically qualify for them, regardless of payer status or ability to pay. The entity or individual furnishing the goods, items and/or services may reasonably limit the aggregate amount it will furnish, provided that the limitation is not based on payer status or ability to pay.

7. ***No Restrictions on Contracting with Other Entities***: The arrangement must not restrict the health center's ability to contract with other providers/suppliers, and the health centers must employ a reasonable selection methodology (*e.g.*, procurement standards).

8. ***Patient Freedom of Choice and Disclosure of the Arrangement***: The health center must effectively notify patients of their freedom to choose any willing provider/supplier, as well as disclose the existence and nature of the arrangement to any patient who inquires.

The final rule also includes an optional standard, under which a health center may require the entity or individual providing it with discounted or no charge goods, items, services, *etc*., to charge referred health center patients no more than the rate it charges other similarly situated patients. By choosing this option, health centers can prevent the entity/individual from overcharging patients as a way to recoup the amount of the discount provided to the health center.

The final rule is available by browsing the October 4, 2007 issue of the *Federal Register* at www.gpoaccess.gov/fr/index.html. For additional information, including examples of real-life arrangements impacted by the safe harbor, please see the NACHC Medicare & Medicaid Technical Assistance Issue Brief # 91: *The Health Center Safe Harbor Rule: What is It and What Does It Mean For You?* (January 2008).

CMS ISSUES FINAL RULES IMPLEMENTING THE STARK LAW

On September 5, 2007, the Centers for Medicare and Medicaid Services (CMS) published the third phase of the regulations implementing the federal physician self-referral law, 42 U.S.C. § 1395nn *et seq*. (the "Stark Law") (72 Fed Reg. 51012). The regulations were effective December 4, 2007.

The Stark Law prohibits a physician (or an immediate family member) who has a financial relationship with an entity (either an ownership interest or a compensation arrangement) from referring a Medicare patient to the entity for one of ten health care services specified in the statute, referred to as a "designated health service," unless an exception set forth in the statute or regulations applies. Moreover, the entity providing the designated health service cannot bill Medicare for a designated health service provided under a prohibited referral.

The regulations contain a new provision under which a physician would "stand in the shoes" of his or her "physician organization" when the physician organization has a compensation arrangement with another health care entity. For example, if a physician organization had a contract with a hospital to provide services, a physician member of the organization would "stand in the shoes" of the organization and be deemed to have a direct compensation arrangement with the hospital. In that case, the physician could not refer a patient to the hospital for a designated health service unless the compensation arrangement between the hospital and the physician complied with the Stark law.

Because the definition of "physician organization" in the final Stark regulations is not clearly defined, NACHC was concerned that the "stand in the shoes" rule, if applied to health center physicians, would effectively negate the benefits of the health center safe harbor (see above) because the low-cost and no cost compensation arrangements that are protected under the safe harbor would not be permitted under the Stark Law. Thus, many arrangements that the safe harbor was designed to permit, and the intended benefits to health centers, would not have been realized.

However, at NACHC's urging, CMS clarified that an FQHC is *not* considered to be a "physician organization "for purposes of the Stark Law. Accordingly, the "stand in the shoes" rule does not apply to FQHC physicians. (CMS's response can be found on the CMS website www.cms.hhs.gov, question ID 8883 under the "questions" tab)

Finally, while the Stark Law technically applies to referrals of Medicaid a patient, CMS has not yet published regulations explaining how Stark applies to Medicaid, and has not indicated when it might do so. Statements in the preamble to the final regulations indicate that CMS will continue to re-evaluate its interpretation of the law and regulations, and it is therefore likely that there will be future, perhaps significant, modifications to the physician self referral rules.

The final rule is available by browsing the September 5, 2007 issue of the *Federal Register* at www.gpoaccess.gov/fr/index.html.

OIG ISSUES NEW ADVISORY OPINION APPROVING DRUG PAP INVOLVING HEALTH CENTERS

On February 1, 2008, the OIG issued its first advisory opinion for FY 2008 (Advisory Opinion 08-01), approving a "bulk replacement" patient assistance program (PAP) which provides free drugs in bulk quantities to participating FQHCs (and free clinics). Under the arrangement, participating drug companies contract with a nonprofit corporation, which imposes uniform PAP operating standards on the participating centers, including:

- Establishing and maintaining separate records and inventory systems.
- Establishing and maintaining computerized dispensing systems that generate reports for monitoring compliance with the program standards and requirements.
- Submitting to annual on-site compliance audits.

The PAP drugs are distributed by the FQHCs only to patients who earn less than 200% of the federal poverty level and have no other outpatient prescription drug coverage.

The OIG approved the arrangement based on following safeguards:

- Under the replenishment system, the FQHCs cannot receive a surplus of donated drugs which, in turn, could be diverted to other uses.

- The arrangement is documented in a written signed agreement that covers all of the free drugs provided. The replenishment methodology is fixed and unrelated to volume or value of referrals, and the FQHCs are required to maintain a separate inventory and detailed records regarding the distribution of the PAP drugs, which the participating drug companies monitor.

- The participating drug companies do not control the selection of participating FQHCs.

- The physicians who prescribe the PAP drugs are not compensated for doing so and the FQHCs do not track the physicians' prescribing patterns.

- Neither the nonprofit corporation's staff nor the drug companies' staff is involved in the FQHC's formulary decision-making process.

- The ultimate recipients of the PAP drugs are financially-needy patients who lack prescription drug coverage.

- The nonprofit corporation has certified that there are no other arrangements between the parties to the arrangement.

- The arrangement relates directly to the core clinical services provided by the FQHCs and helps to ensure the availability of safety net services for underserved populations.

As with all advisory opinions, this opinion is limited only to the particular requesting parties and binds only the OIG (and not other governmental agencies). Thus, it should be used as precedent for similar transactions. However, the advisory opinions provide insight as to the OIG's enforcement considerations and, ultimately, can open the door to OIG approval of similar transactions.

Further information on this advisory opinion, as well as other OIG materials regarding fraud and abuse, is available at www.oig.hhs.gov/fraud.html.

MEDICAID REIMBURSEMENT CASE LAW

FOURTH CIRCUIT DECISION REQUIRING MEDICAID MANAGED CARE PAYMENTS TO MARYLAND HEALTH CENTER

In *Three Lower Counties Community Health Services, Inc. v. Maryland*, 498 F. 3d 294 (4th Cir. 2007) a Maryland health center that was experiencing significant and continual delays in receiving its supplemental payments challenged Maryland's method of making supplemental payments as part of the State's Medicaid managed care program. The health center also challenged the fact that it received no payments at all for services provided to Medicaid managed care enrollees on an "out-of-network" basis (*i.e.*, when health center is not part of provider network).

The Court found that the way in which the State made payments to the health center violated federal law in two significant ways.

- First, the State failed to make full supplemental payments to the health center in accordance with the schedule required by federal law. Federal law was clear and unambiguous in requiring that full supplemental payments be made at least every four months. The State's excuses as to why making full payment took longer than four months were unavailing.

- Second, the Court found that the State failed to make or arrange for payments for services provided by the health center to Medicaid managed care patients on an "out-of-network" basis when those patients presented to the health center and "immediately required [services] due to an unforeseen illness, injury, or condition." 42 U.S.C. §1396b (m) (2) (A) (vii). The federal court decided that the Medicaid Act requires either the State or the managed care organization to compensate a health center for emergency services provided to Medicaid patients even if the health center does not belong to the network of the managed care organization in which patients are enrolled.

As to these two findings, the Court of Appeals remanded the case to the District Court for implementation of the Court of Appeals' decision.

OTHER FEDERAL AGENCY ACTIVITIES AND DEVELOPMENTS

DHHS ISSUES PROPOSED REVISIONS TO THE DEPARTMENTAL APPEALS BOARD'S ADMINISTRATIVE REVIEW PROCESS

On December 28, 2007, DHHS published a notice of proposed rulemaking to revise regulations governing various administrative review processes conducted by the DHHS Departmental Appeals Board (DAB) to ensure that the final decisions take into account and reflect the opinion of DHHS (72 *Fed. Reg.* 73708). Current regulations set forth at 45 C.F.R. § 16 (which govern the review of grant disputes) do not require the DAB to follow published (publicly available) guidance issued by DHHS or the appropriate administering agency. Thus, the DAB decision is the final administrative decision of DHHS regarding such disputes, with no subsequent Secretarial review. The DAB also has final agency authority and review over, among other things:

- Disputes over the imposition by the OIG or CMS of Civil Monetary Penalties (CMPs), exclusions, and assessments related to the health care industry.
- Medicare and Medicaid reconsideration and appeals process.
- Disputes over the imposition of CMPs in connection with HIPAA violations.
- Enforcement sanctions imposed under Medicare Advantage and Medicare Part D.

The proposed rule makes the following changes regarding grant disputes (and similar amendments to the other non-grant related review processes over which the DAB presides, as discussed above).
:

- Clarifies that the DAB must follow published guidance issued by the Secretary or the appropriate administering agency to the extent that such guidance is not inconsistent with applicable statutes and regulations.

- Provides an opportunity for Secretarial review of the DAB's decisions to correct errors in the application of law, or deviations from published guidance. (Note that this change would not impact disputes regarding requirements set by grant terms and conditions, which are determined in the discretion of the awarding agency).

DHHS stated that the final rule would be effective prospectively, and would not affect final decisions that have been issued by the DAB prior to the effective date. The final rule, however, would affect cases that are still under DAB review as of the effective date of the final rule.

The proposed rule is available by browsing the December 28, 2007 issue of the *Federal Register* at www.gpoaccess.gov/fr/index.html.

IRS ISSUES FINAL REVISED FORM 990

On December 20, 2007, the Internal Revenue Service (IRS) released a revised Form 990, the form that charities and other tax-exempt organizations are required to file annually. The new Form 990 will be used for the 2008 tax year (that is, returns filed in 2009)

The final version of the form reflects many of the comments that the IRS received on its proposed revisions that were published for public comment in June, 2007. While the redesigned form maintains the basic format of a core form and a series of schedules, the IRS changed the core form to allow an organization to describe its mission and most significant activities, its governance structure and staffing, and basic financial information up front, with a short summary of each on the first page. The IRS believes that this approach not only will promote transparency but also will provide an exempt organization with the opportunity to describe its accomplishments in significant detail. With its ready availability through the internet, Form 990 increasingly is used by funders, regulators, and others interested in learning more about an exempt organization; as such, health centers should give thought to how they portray themselves on Form 990.

Core Form: The revised Form 990 also exemplifies the IRS view that a well-governed organization is more likely to be compliant with the tax laws. Thus, the new Form 990 asks for information on numerous governance and operational practices that do not necessarily reflect specific legal requirements for exemption. For example, tax-exempt organizations are asked to provide information regarding:

- Board composition.
- How the organizations documents board and committee actions.
- Whether there is a written whistleblower policy.
- Whether there is a document retention and destruction policy.
- Whether there is a conflict of interest policy and, if so, how conflicts are disclosed.
- The process used to determine executive compensation.
- The process (if any) for board review of Form 990 before filing.

Schedules

The core form is supplemented by up to 16 individual schedules, the specific schedules to be filed depending on an organization's individual operations and activities. While it is unlikely that a health center would have to complete more than a few of the 16 forms, schedule "H," which is required for tax-exempt "hospitals," could prove to be particular burdensome.

Schedule "H" is designed to elicit information documenting that a tax-exempt hospital provides a "community benefit" necessary for tax-exemption. As originally proposed, the IRS defined "hospital" broadly enough to include health centers. While there is no doubt that health centers meet the "community benefit" standard for tax-exemption, the amount and type of information requested on Schedule H could prove to be costly and time consuming to compile.

The IRS has indicated that it will define "hospital" for purposes of Schedule "H" according to state licensing requirements. However, it reserved a decision on whether it will require other tax-exempt health care providers to complete Schedule H until it issues the instructions for completing the revised Form 990. To date, the instructions have not been published - NACHC will update health centers on further developments. (NOTE: If required, Schedule H reporting is not likely to have a significant impact on health centers immediately as the IRS deferred most of the reporting requirements until the 2009 tax year).

Further information on the new Form 990 and copies of the form and schedules, as well as other tax-related documents applicable to charities and other nonprofits, is available at www.irs.gov/charities/index.html.

IRS ANNOUNCES PLANS TO CONTINUE EXAMINATION OF EXECUTIVE COMPENSATION

On December 13, 2007, the IRS issued its FY 2008 Implementing Guidelines for Exempt Organizations. The work plan indicates that, among other activities, the IRS intends to continue examining executive compensation issues, including a series of initiatives related to last year's Executive Compensation Compliance Initiative. These initiatives include:

- Continuing Phase III of the Executive Compensation Compliance Project, involving 200 compliance checks and 50 additional single-issue examinations focusing on organizations with loans to officers, directors and trustees.
- Continuing executive compensation examinations initiated in the Hospital Compliance Project.
- Conducting over 90 limited scope field examinations regarding the compensation practices of small and mid-size tax-exempt organizations.

The work plan also indicates that the IRS intends to develop and issue formal guidance to assist tax-exempt organizations in understanding their tax law obligations including:

- Publication of regulations to implement the Form 990 revisions.
- Final regulations under Internal Revenue Code Sections 501(c) (3) and 4958 (Intermediate Sanctions) on revocation standards for organizations that engage in excess benefit transactions.

The IRS FY 2008 Implementing Guidelines are available at www.irs.gov/pub/irs-tege/fy08_implementing_guidelines.pdf.

IRS ISSUES DIRECTIVE ON HOSPITALS PROVIDING FINANCIAL ASSISTANCE TO STAFF PHYSICIANS INVOLVING ELECTRONIC HEALTH RECORDS

In May, 2007, the IRS issued a policy directive allowing tax-exempt hospitals to provide, within certain parameters, electronic health record software and technical support to physicians with admitting privileges without violating the prohibition on excessive private benefit or private increment. The IRS directive parallels "safe harbors" issued by DHHS that allow hospitals to provide such assistance without violating the federal anti-kickback statute or the Stark Law. Accordingly, the IRS directive makes it clear that the arrangement must comply with the DHHS safe harbors in order to be protected for federal tax-exemption purposes. Further, under these arrangements:

- The physician must contribute a portion of the cost of the software and/or technical services that the hospital provides; and
- The hospital must provide the same level of subsidy to all of its medical staff physicians or vary the level of subsidy by applying criteria related to meeting the healthcare needs of the community.

Further information on the IRS Directive is available at www.irs.gov/charities/index.html.

IRS ISSUES REVENUE RULING ON POLITICAL CAMPAIGNING ACTIVITIES OF CHARITABLE ORGANIZATIONS

Charitable organizations that are exempt from federal income tax under Section 501(c)(3) of the Internal Revenue Code are prohibited from becoming directly or indirectly involved in the campaigns of candidates for political office. However, this prohibition does not extend to the personal activities of individual employees and officers of a charity. On June 18, 2007, the IRS issued a revenue ruling designed to help charitable organizations understand the ban on political campaign activities, including, among other things, how personal political activity differs from organizational activity (Rev. Rule. 2007-41, 2007-25 I.R.B). The ruling outlines 21 scenarios that a charity may encounter in the course of a political campaign, and discusses the tax consequences of each.

While the revenue ruling is helpful in understanding how the IRS would evaluate the particular situations described in it, the IRS looks to the "facts and circumstances" of each individual case to determine if a violation has occurred. Thus, the ruling is of limited use in situations that differ significantly from those described in the ruling. Health centers are well advised to seek expert advice in those circumstances.

Further information on political campaign activity is available at www.irs.gov/charities/index.html.

CORPORATE RESPONSIBILITY-RELATED INITIATIVES

In October, 2007, the Panel on the Nonprofit Sector published a final version of *Principles for Good Governance and Ethical Practice: a Guide for Charities and Foundations*. The guidance is organized around thirty-three concepts of "sound practices" which are categorized under four main categories. These concepts include:

- Actions required by all charitable organizations (such as compliance with applicable law, development of conflict of interest policy, maintenance of financial records, development of reimbursement policies, accurate and truthful solicitation materials).

- Actions that each organization should strongly consider, based on its legal and operational structure and particular charitable purpose

The four categories are as follows:

- **Legal compliance and public disclosure** – responsibilities and practices that will assist charitable organizations in complying with their legal obligations and providing information to the public.

- **Effective governance** – policies and procedures that the Board of Directors should consider implementing to fulfill its oversight and governance responsibilities.

- **Strong financial oversight** – policies and procedures that an organization should consider following to ensure wise stewardship of charitable resources.

- **Responsible fundraising –** policies and procedures organizations that solicit funds from the public should consider following to build donor support and confidence.

The Panel indicates that the principals can serve organizations both as guideposts for adopting specific practices that best fit the organization and as tools to evaluate current standards in place. In this regard, the guidance serves as *de facto* best practices for nonprofit sector.

Further information on the guidance is available at www.nonprofitpanel.org.

HHS OIG STUDY ON HEALTH CENTER QUALITY ASSURANCE PROGRAMS

HHS OIG Study on Quality Assurance Programs at Centers in Progress: The HHS Office of Inspector General, Office of Evaluations and Inspections, is conducting a national study of 330-funded health centers related to their quality assurance programs. Approximately 200 centers, selected on a random basis, were contacted in late January to answer a two-part survey on QA programs and Internal Reviews, and to provide QA Program Details. The survey includes a request for an encrypted electronic list of health center patients that had one or more encounters during the past six months at any of the health center's sites. According to Camille Harper, the OIG study director, the patient information will be utilized to select just a small number of center patients to conduct a complete review of the medical records. OIG spokespersons indicated that patients will not be contacted. The due date for return of the surveys was February 1, 2008; some centers requested and received extensions. The OIG letter assures that only aggregated health center information will be reported and that HIPAA privacy provisions have been met. NACHC met with the OIG study team over a year ago, and had alerted PCAs and centers previously that the study would be coming up. NACHC encouraged centers selected to give this survey their careful attention, and to provide complete information, so that this independent national snapshot will highlight the successes of health center quality assurance programs.
The final report is expected to be released in early 2009.

VACCINES FOR CHILDREN PROGRAM DELGATION OF AUTHORITY ISSUE

Centers Cautioned About Executing Vaccine for Children (VFC) "Delegation Agreements" with Health Departments Until Federal Agencies Issue Written Guidance: Many state and local health departments, with encouragement from CDC and ASTHO, are approaching health centers urging them to "delegate authority" that FQHCs have under the VFC statute to administer free VFC vaccines to under-insured children to health departments. Unfortunately, the VFC statute does not give such authority directly to health departments, nor does it clearly authorize FQHCs to delegate their authority to other entities, including those that serve non-health center patients or patients drawn from beyond the health center's service area. NACHC's legal counsel and HRSA's attorneys have raised questions about the statutory authority for such agreements as they are being crafted. NACHC has talked with CDC, HRSA, and ASTHO and urged HRSA or another appropriate agency to issue written guidance clarifying whether health centers do or do not have the authority under current law to execute such agreements without risk of potential allegations of illegally diverting VFC vaccines. NACHC has also offered to work with ASTHO to seek legislation to add state and local health departments to the list of organizations authorized to directly access free VFC vaccines for under-insured children. Until either written guidance or legislative change occurs, NACHC discourages health centers from going forward with such agreements. While NACHC strongly supports full immunization for all children, it needs to happen in a way that does not place health centers at risk.