Congress and the Obama administration took a historic step toward expanding access and improving health care for all Americans in passing health reform legislation last month. The most comprehensive health reform in decades, “The Patient Protection and Affordable Care Act (HR 3590),” was built upon through subsequent legislation “The Reconciliation Act of 2010 (HR 4872),” also passed by Congress and signed into law by President Obama last month.

The health reform legislation focuses primarily on expanding insurance coverage and increasing its affordability, reducing health care costs, and transforming care delivery. Eventually, the legislation aims to ensure coverage for 32 million people—meaning more than 94 percent of all legal U.S. residents will be covered. However, reforms laid out in the bills will not be implemented immediately, and some of the most important provisions will not go into effect for years. Significant responsibility for carrying out health reform goes to the Department of Health and Human Services (HHS); H.R. 4872 appropriates $1 billion to HHS for enactment. Table 1 shows when provisions of the health care legislation become effective and highlights components pertinent to the kidney care community, and can also be downloaded as a pdf from ASN’s Kidney News website at http://asn-online.org/publications/kidneynews/.

Many aspects of these broad reforms—greater access to coverage, emphasis on prevention, closure of the donut hole, expansion of comparative effectiveness research—will almost certainly influence patients at every level in the coming years, including those with kidney disease. Health reform does not address kidney disease at length, but there are a number of key sections of interest for the nephrology community in the 2400-plus pages of legislation.

Models of care delivery
Transforming the delivery system is a primary focus in the health care bill. The legislation paves the way for a host of pilot programs and enables physicians to begin sharing in savings derived from improved care delivery as early as 2010.
Health care reform

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able Care Act establishes a "shared savings program" through which groups of providers coordinate care for Medicare beneficiaries in accountable care organizations (ACOs). ACOs—which are groups of providers and suppliers with shared governance that meet quality performance standards determined by the HHS secretary—will be eligible to receive payments for shared savings beginning January 1, 2012. Intended to promote efficient service and accountability for a patient population, the ACO program encourages investment in infrastructure and redesigned care processes. Among other things, qualified ACOs must prove clinical and patient engagement, such as through the use of individualized care plans.

Although the Act grants the HHS secretary discretion in further defining ACOs, it suggests that ACOs may be formed of an array of providers and organizations, including professionals in group practice arrangements, networks of individual practices, and hospitals employing ACO providers. This inclusive model would afford nephrologists numerous avenues to participate in an ACO—and potentially to improve the delivery and quality of care for patients with kidney disease at any stage of progression from stage I through dialysis.

In addition to the ACO program, the Act creates a Center for Medicare and Medicaid Innovation (CMI) within CMS, tasked with testing innovative payment and service delivery models beginning no later than January 2011. The HHS Secretary will select for testing models that address a specific population for which a care deficit exists, or a population with potentially avoidable expenditures. The patient-centered medical home (PCMH) model and Healthcare Innovation Zones (HIZ) are among possible opportunities for funding and investigation in the legislation. The PCMH concept has received increasing attention within the nephrology community as a possible opportunity to better harmonize care (1). Potentially, nephrologists could provide care and receive payment as a "neighbor" to the medical home, or serve as the "home," for some patients. HIZs—groups of providers including a teaching hospital, physicians, and other clinical entities—would receive a comprehensive payment for delivering a full spectrum of coordination.

Integrated care

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Table 1. Implementation timeline

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<th>Implementation Year</th>
<th>Legislation</th>
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| 2010                | - Bars insurance companies from rescinding coverage when enrollees get sick  
                    | - Requires insurance companies to cover preventive services (applies to plans that are new in 2010)  
                    | - Eliminates lifetime limits on benefits in group health plans and bars plans from imposing pre-existing conditions on children’s coverage  
                    | - Provides sliding scale tax credits to help small businesses afford insurance  
                    | - Reduces the Medicare prescription drug donut hole in 2010 and eliminates it by 2020  
                    | - Establishes an independent, nonprofit institute for comparative effectiveness research |
| 2011                | - Allows unused Graduate Medical Education training slots to be redistributed to increase primary care training at other sites  
                    | - Increases reimbursement for primary care services under Medicare and Medicaid (2013-2014)  
                    | - Establishes a “shared savings program” among which groups of providers may manage and coordinate care in “accountable care organizations” (ACOs) and receive payments for shared savings |
| 2012                | - Establishes a national pilot program on payment bundling to encourage provider collaboration and care coordination  
                    | - Requires drug, device, and other medical manufacturers to routinely submit records of payments or other transfers of value to physicians to the HHS secretary |
| 2013                | - Bars insurance companies from discriminating based on pre-existing conditions, health status, age, or gender and from imposing annual limits on coverage  
                    | - Increases Medicaid eligibility to 133 percent of the Federal Poverty Level for all non-elderly individuals  
                    | - Provides federal matching payments to states for the cost of services to newly eligible Medicaid enrollees  
                    | - Creates health insurance exchanges—competitive marketplaces where individuals and small businesses can buy affordable health care coverage  
                    | - Provides sliding scale tax credits to help individuals afford insurance  
                    | - Requires most individuals to obtain health insurance, or pay a fee if they do not  
                    | - Prohibits health plans from dropping or denying coverage because an individual participates in a clinical trial |
| 2014                | - Establishes an Independent Payment Advisory Board to submit proposals to Congress and the private sector aimed at extending Medicare solvency, lowering costs, and improving health outcomes  
                    | - Creates a value-based (rather than volume-based) physician payment program for Medicare |
| 2015                | - Bars insurance companies from discriminating based on pre-existing conditions, health status, age, or gender and from imposing annual limits on coverage  
                    | - Increases Medicaid eligibility to 133 percent of the Federal Poverty Level for all non-elderly individuals  
                    | - Provides federal matching payments to states for the cost of services to newly eligible Medicaid enrollees  
                    | - Creates health insurance exchanges—competitive marketplaces where individuals and small businesses can buy affordable health care coverage  
                    | - Provides sliding scale tax credits to help individuals afford insurance  
                    | - Requires most individuals to obtain health insurance, or pay a fee if they do not  
                    | - Prohibits health plans from dropping or denying coverage because an individual participates in a clinical trial |

March 31, 2013. All manufacturers of drugs, devices, biologicals, or medical supplies will submit to the HHS secretory detailed documentation of payments made to physicians or teaching hospitals every 90 days. The name and address of recipients, as well as the amount, date, and description of payments are among the information required for all payments or “transfers of value,” including consulting fees, honoraria, gifts, education, research, and travel. The secretary will make payment information publicly available via an Internet database, plus “background information on industry-physician relationships” and “any other information the Secretary determines would be useful for the average consumer.”

The Act contains a limited number of exceptions, including delayed publication of payments made related to research on a potential new medical technology or application, and of those

ices. Also included in the bundle would be payments for acute inpatient care, outpatient and emergency department, and post-acute care services. No date is set for initiation of the pilot program. However, if the secretary determines that expansion of the program would improve—or not reduce the quality of—patient care and reduces costs, he or she must develop a plan for implementation no later than January 16, 2016.

This landmark pilot program marks the first attempt to unite physician fees with other payments since the inception of the Medicare program. Theoretically, the pilot could in the long term prove to be the first step in major changes to the physician payment system.

Industry payments to physicians have long been of interest to Congress, and the Patient Protection and Affordable Care Act will begin bringing these transactions into the public eye as of
made in connection with a clinical investigation regarding a new drug or device. Notably, nephrologists, like other physicians, will not share any reporting burden; the Act places this responsibility solely on industry.

Workforce
The number of U.S. medical students pursuing careers in nephrology has been declining for years, and many consider the lack of student interest in internal medicine residencies to be part of the problem. Seeking to address this shortfall of general interest and other primary care physicians, Congress included numerous approaches to encourage more students to go into primary care.

In addition to multiple incentive payment programs and loan repayment options for students entering primary care, the bill also distributes 65 percent of currently unused residency training slots and directs those slots to hospitals in certain states in July 2011. "The nation’s medical schools and teaching hospitals have expressed their full support for this bill to President Obama," said Association of American Medical College (AAMC) President and Chief Executive Officer Darrell G. Kirch, MD (2).

Comparative effectiveness research
"The most significant thing [in the health care bill] is comparative effectiveness research," said NIH Director Francis Collins, MD (3). Indeed, the legislation establishes a "Patient-Centered Outcomes Research Institute," an independent, nonprofit corporation to increase the quality and relevance of medical services and treatment through comparative effectiveness research. The institute is tasked with identifying national priorities for comparative effectiveness research, including cost-effectiveness of interventions, disease incidence, prevalence, and burden—and emphasizing chronic conditions and gaps in evidence in terms of clinical outcomes, among other factors. In carrying out its research agenda, the institute will enter into contracts and grants funding for medical research

Proposed budget includes robust funding for medical research
Requesting a $1 billion increase in discretionary NIH funding for FY 2011—a 3 percent increase from FY 2010 levels—President Obama highlighted priority areas in his budget request (Table 1). Of the total $32.2 billion requested for NIH for FY 2011, approximately $1.96 billion is targeted toward the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), a 2.6 percent jump from FY 2010. Similarly, the budget includes a 2.9 percent increase over last year for both the National Heart, Blood, and Lung Institute (NHLBI) and the National Institute on Aging (NIA), nearly $3.1 billion and just over $1.1 billion, respectively.

NIH Director Francis Collins, MD, recently outlined five "exceptional opportunities" for the agency to pursue that could reap substantial downstream benefits. In developing the budget, NIH mapped the portfolio of each institute or center against these five themes and then adjusted to reflect other area-specific contingencies:

- Applying high-throughput technologies to understand fundamental biology and to uncover the causes of specific diseases.
- Translating clinical science discoveries into new and better treatments.
- Putting science to work for the benefit of health reform.
- Encouraging a greater focus on global health issues.
- Reinvigorating and empowering the biomedical research community.

Collins also emphasized medical research as a sound investment in the economy. NIH data show that each dollar of NIH funding creates more than two dollars in state economic output per year, and each grant generates approximately seven jobs.

Although pleased with the proposed increase, the Ad Hoc Group for Medical Research, on whose executive committee ASN serves, had recommended that NIH receive a $35 billion budget in FY 2011. This figure reflects the FY 2010 budget adjusted for medical inflation, plus half of the value of funds that were awarded as part of the American Recovery and Reinvestment Act (ARRA, better known as the economic stimulus package), to ensure continuation of ongoing research.

Last year, Congress appropriated the Department of Veterans Affairs (VA) approximately $47.5 billion in discretionary funding for medical care and an additional $34.5 billion in non-discretionary health research. For FY 2011, the Obama administration proposes a nearly 8.5 percent boost in medical care spending totaling over $51.5 billion.

VA health research also stands to gain—if somewhat more modestly—at 1.5 percent over FY 2010 levels, or just shy of $600 million. ASN serves on the executive committee of the Friends of the Veterans Affairs Medical Care and Health Research (FOVA), which has recommended a $700 million research budget to support returning veterans from Iraq and Afghanistan and to bring VA research facilities into the 21st century.

Comparative effectiveness research gets likely boost
With a proposed budget increase of 5.4 percent above FY 2010 funding, AHRQ receives the largest budget boost of any health-related agency in the president’s budget. The $611 million outlined in the request is nearly $214 million more than AHRQ saw last year. Given the administration's focus on health reform, AHRQ—charged with research within health care quality, reduces costs, and broad access to essential services—a is a high funding priority.

If the president’s proposal is enacted, a substantial portion—approximately $272.5 million—of the total $611 million AHRQ budget will likely be targeted to expand comparative effectiveness research. Other priorities for research within AHRQ are aimed at building the science and technologies intended for use in comparative effectiveness research. The institute will enter into contracts to support funding needed to build the science and technologies intended for use in comparative effectiveness research.