

In this issue

The summer has been a particularly busy season for the people at HHS and CMS who have been working on matters critical to the healthcare provider community. Matters include Medicare and Medicaid spending, healthcare information technology, fraud and abuse, specialty hospitals, and Medicare payment rules—topics to which we devote significant time and space on your behalf in the opening article of this edition.

Reform of our healthcare system is the next subject that we discuss this quarter: first as a supplement to the commentary in recent editions of *KPMG's Healthcare Business Briefing*, and second due to the great importance of this subject for our clients in the United States.

In our next article, "On the Hill," we begin with pension reform, an issue that has been a major topic on the Hill for quite a while; and finally a bill has been passed and signed by the president. This legislation will affect all of us as individuals, regardless of our employer. We also have a few words on healthcare information technology legislation passed by the House that will now go to a House-Senate conference.

We move next to recent matters here in Washington concerning the pharmaceutical field, concentrating on actions by the Food & Drug Administration. We then provide some brief comments about a proposed SEC rule that would bring some temporary relief to smaller companies with respect to Sarbanes-Oxley compliance. We wrap up with our End Notes—a brief commentary on various matters that we trust will interest you.

Just as we went to press, CMS Administrator Mark McClellan resigned, which was not unexpected. His successor, we believe, will soon be announced by the administration.



"Unless we can find some way to keep our sights on tomorrow, we can't expect to be in touch with today."

*Dean Rusk,
Former U.S. Secretary of State*

Medicare and Other HHS- CMS- Related Matters

Medicare/Medicaid Spending

Earlier this summer, CMS Administrator Mark McClellan indicated that, despite projections of falling costs for prescription drugs under the Medicare Part D benefit (\$34 billion lower for the 5 years ending in 2010 than in the president's fiscal 2007 request budget and \$110 billion lower than predicted in 2005), Medicare Part A and B spending continues to increase rapidly, requiring payment reforms. He emphasized the need for Medicare to pay more accurately and to reward better care, not simply paying for more services. A reform example cited was paying hospitals, physicians, and other providers for delivering care more efficiently.

Medicare Part A and B spending is higher primarily due to the continuing rapid growth of services. Part A expenditures from 2006 to 2010 are expected to be \$17 billion higher and Part B's approximately \$30 billion higher than in the president's most recent budget request. According to CMS, rapid growth in spending for physician-related and hospital outpatient services is principally responsible for the projected 11 percent increase in Medicare premiums next year.

Medicaid spending projections meanwhile are down according to CMS, reflecting effective federal and state steps to slow spending growth. The agency projects that for fiscal 2006 to 2015, federal Medicaid costs will be \$224 billion lower than had been projected a year ago—an 8 percent decline. The slowdown is attributed to steps such as state cost containment strategies, federal and state collaboration through waivers, innovative state plan amendments to deliver services more

effectively, new tools to reduce the growth in the cost of prescription drugs, and increased oversight by the federal government to prevent fraud. Related to Dr. McClellan's comments in July, in late May he said the agency has shifted focus from enrolling Medicare beneficiaries in Part D to the use of prevention services.

A report this summer by Premier Inc. on the results of the CMS/Premier Inc.

fewer readmissions, 6,000 fewer medical complications, and 500,000 fewer days in the hospital. For more information, please go to www.premierinc.com.

Healthcare IT/e-Sharing

- On August 1, HHS Secretary Leavitt announced **final regulations that will support physicians' adoption of electronic prescribing and electronic health records technology.** The final rules create new exceptions

Percentage Increase in Part A Hospital Spending

	2002	2003	2004	2005*	2006 (est.)
Inpatient Acute Care Hospitals	7%	3%	7%	4%	3%
Inpatient Rehab Hospitals	21%	10%	4%	1%**	1%**
Long-Term Care Hospitals	22%	19%	21%	17%	7%**

* Overall Part A spending increased more than 7 percent in 2005

** Declines attributed by CMS to payment reforms

(Source: CMS Office of the Actuary)

Percentage Increase in Part B Volume/Intensity

	2002	2003	2004	2005 (est.)*	2006(est.)
Physicians' Services	6%	5%	6%	7%	6%
Outpatient Hospital Services	3%	2%	8%	8%	10%

* Overall Part B spending increased by 11 percent in 2005; physicians' services spending grew by 10 percent and outpatient hospital services grew by 11 percent

(Source: CMS Office of the Actuary)

Hospital Pay for Performance (P4P) demonstration indicated that better care cuts health costs. For example, instituting a series of basic, widely accepted care procedures for 75,000 patients undergoing care for pneumonia and heart bypass surgery would have reduced hospital costs for the patients by as much as \$1 billion. The report also concluded, among other things, that providing this level of care would have resulted in 3,000 fewer deaths, 6,000

and safe harbors to certain federal fraud and abuse laws for arrangements involving the donation of certain electronic health information technology and services. Specifically, the exceptions and safe harbors establish conditions under which:

- Entities furnishing designated health services and other items may donate to physicians and certain other recipients interoperable electronic health records software,

information technology and training services that are necessary and used predominantly to create, maintain, transmit, or receive the e-records of the donor's or physician's patients.

- Hospitals and other specified entities may provide physicians and other recipients with hardware, software, information technology and training services necessary and used solely for electronic prescribing. The services and items must be provided by a hospital to a physician who is a member of its medical staff, by a group practice to a physician who is a member of the group, or by a prescription drug plan sponsor or Medicare Advantage organization to a prescribing physician. The donor or any person on the donor's behalf may not take any action to limit or restrict the use of compatibility of the items or services with the e-prescribing or e-health records systems, among other criteria.

The goals are to improve care by giving doctors and other providers needed support for interoperable health records to enable them to increase the quality of care and to improve efficiency, and to help promote the adoption of essential health information technology while protecting federal health programs and beneficiaries from fraud and abuse.

The scope of donors and recipients is considerably broader than in previously proposed rules. Donations protected under the exception may be made to any physician by entities furnishing designated health services. The exception requires compliance with criteria similar to those listed in the e-prescribing

exception as well as additional criteria, such as those requiring cost sharing and selection of physician recipients of donated technology.

The corresponding safe harbor is similar and covers a broad array of providers, suppliers, practitioners, and health plans when they provide e-records technology to physicians and others delivering care.

The specifics may be found at: www.cms.hhs.gov, www.cms.hhs.gov/apps/media/press/release.asp?Counter=1920, and www.oig.hhs.gov.

- As we were preparing this *Update* for you, HHS Secretary Leavitt indicated that the president will sign an executive order **requiring all Medicare providers to adopt quality measurement and reporting tools and uniform IT standards**. The secretary indicated that many large employers may be required to do the same regarding the providers with whom they contract. The standards will cover functions relating to registering patients, reporting laboratory results, writing prescriptions, and providing secure communications between providers and patients.
- In another IT-related matter in Washington, D.C., the HHS Secretary announced in mid-July that **the first ambulatory electronic health record products have been certified by the Certification Commission for Healthcare Information Technology (CCHIT)**. Twenty products received certification after undergoing inspections that demonstrated 100 percent compliance with established criteria that are established to ensure products (1) provide a broad foundation of functionality, (2) will evolve to be

interoperable with other systems, and (3) include security features that protect the privacy of personal health information.

- We also wanted to mention to you that **HHS is drafting another executive order that the president is expected to sign. This one would require all providers of Medicare services and other federally financed healthcare programs to agree to basic cost measurement tools, followed by quality of care measurements or transparency measures, if you will.** In essence, the draft order would require U.S. government contracts with health plans to stipulate that covered medical providers will be willing to use IT that meets federally approved standards for efficacy and interoperability. The initial requirements would call for plan-covered clinicians to agree to use the following technologies:
 - Electronic registration technology enabling patients to instantly provide basic demographic, medication, allergy, and diagnostic information at their initial office visit
 - Electronic versions of lab results that can be easily be shared with other providers
 - Electronic prescription technology providing patient-specific safety medication checks, and secure legible transmission of prescriptions to pharmacies
 - Secure electronic messaging systems allowing patients to communicate
 - Technology systems that have been certified by the CCHIT.
- Since June 1, Medicare has been posting information on its Web site for public consumption concerning the prices that it pays for 30 elective inpatient hospital procedures as well as other information on hospital

admissions by hospital, by county. CMS also has plans to disclose information for common elective procedures by ambulatory surgery centers and common hospital outpatient and physician services. Please refer to www.cms.hhs.gov/HealthCareConInit/01_Overview.asp.

Fraud & Abuse

- According to the HHS Office of the Inspector General, for the six months ending March 31, 2006, investigations and audits by the office are expected to return more than \$1 billion to federal programs: \$288 million is expected from audits and \$732 million from investigations. For more information, please go to: www.oig.hhs.gov/publications/docs/semiannual/2006/Semiannual/Spring2006.pdf
- In mid-July, CMS launched a new Medicaid Integrity Program created by the Deficit Reduction Act of 2005. The new program will be based on four key principles:
 - National leadership in Medicaid program integrity
 - Accountability for the program's activities and for those of its contractors and the states
 - Collaboration with the internal and external partners and other stakeholders
 - Flexibility to address the ever-changing nature of Medicaid fraud

To achieve its goals, the program will employ several major strategies, such as:

- Collaboration and coordination with internal and external partners
- Consultation with interested parties in the development of the comprehensive Medicaid integrity plan
- Targeting vulnerabilities in the Medicaid program

- Balancing the roles of providing training and technical assistance to states while conducting oversight of their activities, and supporting criminal investigations of suspect providers while concurrently seeking administrative sanctions
- Employing lessons learned in developing guidance and directives aimed at fraud prevention
- Developing effective return on investment strategies

Report on Specialty Hospitals

Before we move to the specifics regarding a myriad of Medicare provider payment rules, we wanted to offer a few words on a CMS report to Congress on specialty hospitals. The report outlines the agency's intention to implement a strategic plan for specialty hospitals that addresses physician ownership in these hospitals and simultaneously ends an administrative moratorium on specialty hospital enrollment in the Medicare program as required by the 2005 Deficit Reduction Act.

According to Dr. McClellan in August, "The steps we are talking in our final report will not only promote high-quality, appropriate care in specialty hospitals, but will also encourage appropriate hospital care for all patients, and better information about the financial arrangements involved in hospital care as well."

The plan outlined in the report:

- Highlights the importance of moving forward with the major payment reforms to the hospital inpatient prospective payment system (IPPS) and ambulatory surgery centers (ASCs) systems initiated by CMS. By eliminating the sometimes large differences between payments and costs for some types of hospital

care, CMS is looking to eliminate improper incentives for physicians and hospitals to invest in services simply because they are the most profitable.

- Includes new approaches for implementing gain-sharing and value-based payment approaches as a means to align physician and hospital incentives while achieving measurable improvements in quality of care
- Contains transparency of investment initiatives: hospitals will be required to provide CMS information concerning physician investment and compensation arrangements and to disclose to patients whether they have physician investors
- Announces CMS's position that non-proportional returns on investments and non-bona fide investments may violate the physician self-referral statute and are suspect under the anti-kickback statute
- Provides guidance concerning what is expected of hospitals that do not have emergency departments under the Emergency Medical Treatment and Labor Act and changes in the enrollment form to identify specialty hospitals
- Indicates that failure to provide data required in the plan will result in penalties of as much as \$10,000 for each day that requested data is not submitted

More information can be found at: www.cms.hhs.gov/PhysicianSelfReferral/.

Major Payment Rules Released by CMS

Since we last issued our *Healthcare Update*, CMS has been very busy preparing and issuing various Medicare provider payment rules as the federal fiscal year begins on October 1.

Hospital Inpatient PPS

In the final rule released on August 1, inpatient PPS payments to all hospitals will increase a total of \$3.4 billion in fiscal 2007 or an average of 3.5 percent. Payments to cardiac specialty hospitals will increase on average by only 1.2 percent due to changes by CMS to improve payment accuracy. Payments for inpatient services for operating and capital costs will increase on average by 3.4 percent to all other urban hospitals and by 3.7 percent to rural hospitals, provided that quality data is submitted to Medicare.

Hospitals that do not report quality data will not receive a full market basket increase in 2007. They will receive the market basket less 2 percentage points. Also, approximately 2 percent of all hospitals will experience a payment decrease due to wage index changes. In addition, the 2007 cost outlier threshold will be \$24,475 vs. \$25,530 announced earlier this year in the proposed 2007 rule; the fiscal 2006 threshold is \$23,600.

An area of great contention resulting from the 2007 proposed rule dealt with provisions for improving the accuracy of payment rates by basing Diagnosis-Related Group (DRG) weights on hospital costs rather than charges to eliminate the bias in the current system arising from the differential markup that hospitals assign for ancillary services among DRGs and adjusting DRGs for patient safety/severity of illness. In response to comments from the public and some members of Congress, the final CMS rule contains some revisions to the proposed methodology. Briefly:

- No DRG weight will decrease by more than 5.4 percent in fiscal 2007 and 10 DRG weights will increase by more than 5 percent.

- CMS has refined the methodology for determining average costs per case at the DRG level. For example, the number of distinct hospital departments used in the calculations increase from 10 to 13, and more hospital data has been included in the final calculations.
- The change will be phased in over three years beginning this October 1.
- CMS will further evaluate hospital charging practices particularly for expensive items as part of considering further improvements in 2008.
- Regarding severity of illness, in 2007, Medicare will begin the process of moving to more complete severity adjustments by adding 20 new groups to the current DRG system. The agency, in preparation for 2008, will conduct an evaluation, with public input, of alternative systems for more comprehensive severity adjustment as a prelude to making more comprehensive changes to better account for severity of illness.

With respect to some other areas covered in the final rule:

- **Graduate medical education:** the final rule clarifies that in non-hospital settings only the time spent by residents in patient care activities may be counted for the purposes of direct GME and Indirect Medical Education (IME) payments. In the hospital, residents' training in all areas of the hospital may be counted for direct GME purposes but may only be counted for IME purposes when the residents are involved in patient care activities in the inpatient areas of the hospital subject to the inpatient PPS or the outpatient department.

In addition, for cost reporting purposes beginning on or after October 1, 2006,

CMS will implement a "one workday" approach to documentation of residents' time. If a resident's workday consists entirely of scheduled non-patient-care activities, that workday must be identified as non-patient-care time and be subtracted from the allowable count of residents.

- **Hospitals within Hospitals (HwHs):** CMS is revising the rules for grandfathered HwHs, grandfathered satellites of excluded hospitals, and grandfathered satellites of excluded units to allow these facilities to increase or decrease their square footage or decrease their number of beds without jeopardizing their grandfathered status. And, such changes could be undertaken for any reason and would not be limited to situations involving changes in federal, state, or local laws or catastrophic events or the relocation of a facility.

Inpatient Rehabilitation Facilities (IRF)

Also on August 1, CMS announced a final fiscal 2007 Medicare payment rule covering inpatient rehabilitation facilities that provides for a market basket increase of 3.3 percent beginning this October 1. In addition, the rule finalizes requirements of a three-year phase-in of a 75 percent compliance threshold under which three quarters of an IRF's patients must have at least one of 13 designated medical conditions—the particulars are in our *Spring 2006 Update*.

Hospital Outpatient Services

On August 8, CMS issued a proposed rule that, when finalized, will be effective beginning January 1, 2007, and would pay all hospitals a total of \$32.5 billion during the calendar year. The rule contains a 3.4 percent inflation update under the **Outpatient PPS (OPPS)**,

and, after taking into account all factors, providers would receive an average increase of 3 percent in calendar 2007.

In an attempt to promote greater value in Medicare outpatient services, the rule proposes to tie payment rate increases to the reporting of quality measures beginning in 2007. Hospitals that report quality data under the Inpatient PPS would receive a full IPPS update on outpatient payments as well, while hospitals that are required to do so, but do not, would see their outpatient payments reduced by two percentage points. CMS also proposes to move to the use of additional quality measures that are specific to hospital outpatient care. In addition, the maximum payment for emergency department visits will increase to \$345, and to \$133 for clinic visits.

The August 8 rule also proposes changes to payments for **Ambulatory Surgery Centers (ASCs)** to better align payments for surgical procedures provided by ASCs and hospital outpatient departments. In essence, this proposal would allow payment to an ASC for any surgical procedure that does not pose a significant safety risk, expanding by 14 procedures the list of procedures that Medicare will pay for using an ASC facility.

The agency has also proposed adopting relative payment weights under the OPPTS to define the relativity in resource costs among different procedures payable to an ASC. ASC-based payments will be less than those to a hospital department due to the cost differential, and a two-year transition period is proposed for this change. ASC rates would be set using the relative payment weight determined for a particular procedure

multiplied by a conversion factor determined by CMS. For 2008, this is estimated to be 62 percent of the 2008 OPPTS conversion factor. The agency has also proposed revising ambulatory payment classification groupings for drug administration services to allow hospitals to be paid separately for infusion service hours.

Physician Services

While CMS Administrator McClellan expressed concerns about how a reduction in reimbursement could affect quality of care, in early August, as required by statute, CMS proposed that the 2007 physician Medicare payment rates be reduced by 5.1 percent. The reduction results from the use of the Sustainable Growth Rate formula required by law. The proposal, among other things, would also continue a 25 percent reduction in payment for the technical component of multiple imaging procedures on contiguous body parts, versus increasing the reduction to 50 percent as contemplated in the 2006 fee schedule. And it places restrictions on the types of space ownership or leasing arrangements that will qualify under the physician self-referral rules or in-office ancillary services exception. As an aside, in August Dr. McClellan also said that he's optimistic about Congress's making changes this year to the physician payment system.

Home Health

In late July, Medicare announced a proposal for a 3.1 percent average increase in payment rates for home health services in calendar 2007. If they report their quality, urban providers would receive a 2.9 percent increase and rural providers would receive a 3.3 percent increase. As with other affected pro-

viders, if an HHA does not report certain quality data to CMS, its payments will be reduced by 2 percentage points. CMS has also proposed to:

- Revise the payment methodology for oxygen equipment, oxygen contents, and capped rental durable medical equipment
- Establish separate payment classes for new technologies that eliminate the need for refilling and delivery of oxygen contents, the delivery of portable oxygen contents, and delivery of stationary oxygen contents
- Provide additional supplier requirements to safeguard beneficiaries.

Nursing Homes

In late July, the agency announced skilled nursing facility Medicare payments will increase by 3.1 percent in 2007.

A Few Other Matters

- **On August 1 Medicare issued a final rule that establishes requirements for accreditation of suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) and provides the groundwork for timely implementation of a competitive bidding program.** Basically, the rule lays out the application process for the independent accrediting organizations, including those that would participate in the competitive bidding program.
- **National Provider Identifiers (NPIs)** – can be applied for online at www.cms.hhs.gov/NationalProvIdentStand/.
- HHS announced earlier this summer that it will distribute an additional \$225 million in funding for state and local health officials to prepare for a pandemic flu.

Entitlement Reform

More and more here in Washington, D.C., we hear comments about the need to reform our healthcare system. For example, many remarks have been made so far this year by Republicans; Democrats such as Senator Kerry, who advocates a universal system; and others on the Hill, as well as folks representing the administration. We don't expect this trend to end anytime soon as evidenced by the commentary in our last few semi-annual *KPMG's Healthcare Business Briefing* papers.

Most recently, President Bush was quoted in July as saying: "In the long run, the biggest challenge to our nation's economic health is the unsustainable growth in spending for entitlement programs, mandatory programs such as Social Security, Medicare and Medicaid."

The president's new Secretary of the Treasury, Henry Paulson, in his first major policy address called the growth in entitlement programs "The biggest economic issue facing our country."

Comments are certainly not limited to government officials. For example, General Motors Chairman Richard Wagoner told Congress in July that it should pass healthcare information technology legislation (see our next article) and release Medicare claims information to help employers control healthcare cost increases. That said, he is also reported to have said that the rising price of healthcare has made employers willing to work with the Hill on ways to completely overhaul our nation's healthcare system.

CMS Administrator Dr. McClellan also told Congress in July "There is already substantial evidence of overuse, misuse, and underuse of medical treatment that result in potentially preventable complications and higher costs. Yet by paying more for more treatments, regardless of their quality or impact on patient health, our current system does little to address these quality problems and in certain respects could support and encourage less than optimal care."

One thing that we'll be watching for you in the coming months is whether Congress considers and establishes a bipartisan commission or panel of some sort to suggest ideas on how to reform the government's social insurance and health programs—an idea that has been gaining some momentum on the Hill.

On the Hill

After many, many months of deliberation, the Congress has passed and the president has signed H.R. 4, **The Pension Protection Act**. According to a brief summary of the Act, it provides, among other things, for:

- **Stricter funding standards:** Minimum contribution levels will be based on a funding target of pension assets equal to 100 percent of liabilities, up from an effective funding target of 90 percent today. Plans considered to be at risk of termination will be required to fund up to a higher liability level that takes into account potential employee retirement choices that could increase costs. The use of credit balances in lieu of cash to fund required contributions will be restricted.

The target phases in as follows: 92 percent in 2008, 94 percent in 2009, 96 percent in 2010 and 100 percent thereafter. At risk means that the plan is less than 80 percent funded on a normal basis and also less than 70 percent funded when using the higher liability calculation applicable to plans at risk. The 80 percent target also phases in starting at 65 percent in 2008 and rising to 80 percent in 2011. Financially troubled companies considered at risk are also restricted in giving deferred compensation payouts to executives.

- **Benefit restrictions:** Heavily underfunded plans will be restricted from increasing benefits. The most underfunded will be required to freeze

their plans altogether until they are better funded.

- **Higher Pension Benefit Guaranty Corporation (PBGC) premiums:** The bill eliminates an exception that allows most underfunded plans to avoid paying a variable premium based on the amount of their underfunding. Over time, this should lead to higher PBGC premiums and/or reduced underfunding in the system.
- **Changes to calculations of asset and liability values:** Current law allows asset values and interest rates to be averaged over a number of years in order to make contribution requirements more predictable and smoother. Several rule changes substantially reduce the level of smoothing. In addition, rates will

now vary, to some extent, with the length of time until the relevant payments are made.

With respect to 401(k) plans, the law:

- Allows employers to address the inertia that currently hinders many workers from saving by automatically enrolling employees in 401(k) plans unless the employee opts not to be enrolled
- Allows employers to automatically increase the amount of money they deduct from employees' paychecks for contribution to their 401(k) plans over time
- Encourages plan sponsors to offer annuities as a direct distribution option by allowing 401(k) plan assets to be paid out more like the lifelong

income of a traditional defined benefit plan

- Makes permanent a higher catchup contribution limit for workers who need to add to their savings as they near retirement
- Permits employees who participate in 401(k) and 403(b) plans to rebalance their portfolios by changing the particulars of their plans
- Gives employees easy access to advisers who can help them make better savings decisions

In late July, by a vote of 270–148, the House passed the Health Information Technology Promotion Act of 2006, H.R. 4157. The bill now goes to a conference with the Senate. The House bill would codify the Bush

Administration's national coordinator for health IT, create statutory safe harbors to allow hospitals and other providers to provide physicians with IT software and hardware, and require HHS to develop a healthcare IT strategic plan. The Senate version would create a public/private American Health Information Collaboration panel charged with making IT recommendations to HHS within one year of enactment.

At this time, we don't expect any other significant legislation related to healthcare to pass before the November elections, other than perhaps some relief for physicians regarding the Medicare payment formula. If Republicans lose the House this fall, the likelihood of a post-November lame duck congressional session increases.

Some Pharma Matters for Your Consideration

- **Concerned about a possible conflict of interest** in early August, the House Energy and Commerce Committee announced that it is asking the National Institutes of Health (NIH) for details about one of its researchers who is alleged to have worked as a drug company consultant at the same time. The committee says it is seeking to determine if there is a sufficient factual basis to formally investigate questions about NIH policy, the adequacy of its oversight, or other issues that may be raised by the employee's conduct. Whether any legislation regarding such conflicts will result remains to be seen.
- Earlier this summer, in a Commonwealth Fund survey of healthcare leaders, conducted by Harris Interactive, Inc., two thirds of the

leaders said that **the Medicare Part D program, on balance, has been good for beneficiaries.** Surveyed leaders, however, were critical of the availability of coverage exclusively through private plans and the "doughnut hole" coverage gap. Their highest priorities to solve the "gap" problem are some combination of increased co-payments or additional government funding and eliminating the asset test to qualify for a low-income subsidy.

Regarding the private plan exclusivity situation, over 75 percent of leaders favor offering a comprehensive benefits option that combines all Medicare benefits into one package as an alternative to the current policy. Some other changes they favor include eliminating the late enrollment penalty, reducing the complexity of the program, and

allowing Medicare to negotiate drug prices on behalf of Part D beneficiaries.

FDA Matters

In a July report, the HHS Inspector General (IG) said that the FDA is **unable to determine whether or how promptly drug manufacturers are completing post marketing studies, and the agency should require more information in annual status reports (ASRs)** since roughly one third of ASRs regarding post-marketing studies were missing or incomplete. And even complete ASRs contained too little information and were of limited usefulness.

The IG recommended that the FDA (1) instruct drug companies to provide more and better information about post-marketing study commitments, (2) improve the management monitor-

ing system regarding such commitments, and (3) ensure that such commitments are being monitored. The FDA disagreed with the IG's overall conclusion as well as with recommendation (1) above.

A nationwide health professional education campaign to reduce medication mistakes caused by unclear medical abbreviations was launched in June by the FDA and the Institute for Safe Medications Practices (ISMP). The campaign is aimed at reducing the number of common, but preventable, mistakes caused by using unclear medical abbreviations and it recommends consulting the ISMP's list of abbreviations, symbols, and dose designations most often associated with medication errors whenever medical information is communicated. Campaign materials can be obtained at: www.fda.gov/cder/drug/MedErrors and www.ismp.org/tools/abbreviations.

In late June, the agency announced a series of new policy and regulatory developments to strengthen its oversight and protection of patients in clinical trials and the integrity of resulting data in an effort to modernize its approach to bioresearch monitoring.

The Human Subject Protection and Bioresearch Monitoring Initiative will facilitate the modernization of the regulation of clinical trials and bioresearch monitoring, specifically the protection of human subjects and the integrity of data in clinical trials encompassing devices, foods, human drugs, biological drug products and veterinary medicine.

In August, the FDA announced the formation of a nanotechnology task force that, briefly, will:

- conduct a public meeting to help the agency further its understanding of developments in nanotechnology materials that pertain to FDA-regulated products

- assess the current state of scientific information pertaining to nanotechnology materials to help carry out the FDA's mission
- evaluate the effectiveness of the agency's regulatory approaches in this area
- explore opportunities to foster innovation using nanotechnology to develop safe and effective drugs, devices, biologics and other products
- continue to strengthen the FDA's collaborative relationship with other federal agencies
- consider appropriate vehicles for communicating with the public about the use of nanotechnology materials in FDA-regulated products
- submit its initial findings to the Acting Commissioner within nine months of the public meeting

For additional information about the public meeting, please refer to: www.fda.gov/OHRMS/DOCKETS/98fr/06n-0107-nm00002.pdf.



Sarbanes-Oxley Section 404 Compliance

The SEC has issued proposed rules intended to grant smaller public companies additional relief from compliance with Sarbanes-Oxley section 404 internal controls reporting compliance by extending the date by which nonaccelerated filers must begin providing a management assessment of the effectiveness of the entity's internal controls over financial reporting. The initial compliance date for such reports would be moved from fiscal years ending on/after July 15, 2007, until fiscal years ending on/after December 15, 2007.

In addition, the agency has proposed extending the date by which such filers must begin to comply with the section 404(b) requirement to include an auditor's attestation report on internal controls. This deadline would be moved to the first annual report for a fiscal year ending on/after December 15, 2008. The text of the proposal can be found at: www.sec.gov/rules/proposed/2006/33-8731.pdf.

End Notes

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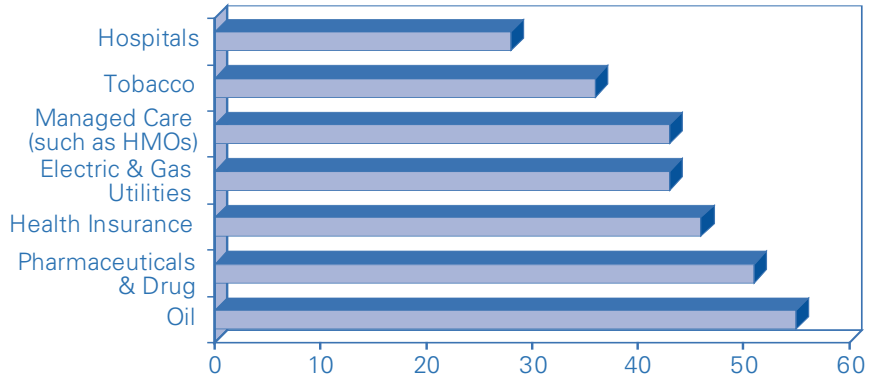
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*"In politics, as in the sickbed,
people toss from side to side
thinking they will be more
comfortable."*

Johann Wolfgang von Goethe

Which Industries Should Be More Government Regulated?



Source: Harris Interactive online survey of 1,823 respondents age 18 and older; margin of error +/- 2 percentage points; reported in USA Today July 12, 2006

- According to Milliman, Inc., the average total medical spending for the typical American family of four was \$13,382 in 2006.
- Based on not-for-profit hospitals' record profitability in 2005, Moody's has predicted a stable outlook for 2007; however, Moody's believes that in order to sustain 2005 performance levels, the not-for-profit sector will have to reverse declining outpatient and inpatient trends and grow service lines. In 2005 median inpatient growth declined 1.2 percent, outpatient surgeries had only a .5 percent growth rate, and the outpatient visit growth rate declined to 2.9 percent.
- The Agency for Healthcare Research and Quality has reported that the percentage of workers enrolled in employer-sponsored health plans that require a co-payment for hospital care increased more than 60 percent between 1999 and 2003 to 54.7 percent.
- The Institute of Medicine has announced that our nation's emergency rooms are overcrowded and underfunded while experiencing a dramatic increase in patient visits, according to three reports issued by the Institute in June of this year. The reports called for increased federal funding for emergency rooms and better coordination of such care among providers, municipalities, states, and federal officials. For more information, please go to: <http://national-academies.org/morenews/20060614b.html>.

