2003 OPPS Rule Means Drastic Cuts for Drugs and Devices

On August 6, the Centers for Medicare and Medicaid Services (CMS) released its proposed regulation setting the rates and policies that will apply to the outpatient prospective payment system (OPPS) in calendar year 2003. The proposed regulation (*http://cms.hhs.gov/regulations/hopps/propcy2003.asp*) was published in the August 9 *Federal Register*, with 60 days for public comment. The final regulation will be published around November 1 and will take effect on Jan. 1, 2003.

ACCC is analyzing the proposal and preparing comments; however, an initial review of the regulation finds that reimbursement for drugs and devices has been drastically reduced, while overall hospital payments have been increased.

The biggest change in the OPPS for 2003 is the fact that the majority of drugs and devices will roll off the pass-through at the end of 2002. All devices losing their pass-through eligibility will have their costs packaged into the costs of the associated procedure. Drugs losing their pass-through eligibility with a median cost of $150/dose or less will also be packaged into an APC for the associated procedure (e.g., chemotherapy infusion). Of the 321 drugs currently paid under the pass-through, 163 would be packaged with their procedures. In 2001, these 163 drugs received $272 million in separate payments. The question is whether the associated procedure APCs will see an aggregate increase of this same amount.

Such an increase seems unlikely, however, since the chemotherapy administration codes were changed as follows:

- "Chemotherapy by infusion alone" decreased by about $4 ($205 to $201): 2001 utilization = 413,000.
- "Chemotherapy by other than infusion" decreased about $2 ($46 to $44): 2001 utilization = 156,000.
- "Chemotherapy by infusion and other technique" increased about $80 ($215 to $295): 2001 utilization = 102,000.

The remaining 158 drugs rolling off the pass-through will continue to receive separate payments for one more year. However, the payment amount will no longer be 95 percent of AWP; instead, payment will be based on the OPPS methodology that compares median cost of the item to the median cost of all services. This new methodology has significantly decreased payments for most of these drugs. Only 11 drugs will increase in payment; five drugs will stay at the same payment level; and 142 drugs (90 percent of them) will decrease in payment. The new payment rates for these 158 drugs result in a reduction of $374 million.

Drugs or devices that joined the pass-through pool on or after Jan. 1, 2001, will continue on the pass-through another year. CMS identified 23 drugs and four device categories that meet this requirement. In addition, new items will be added to the pass-through in the final rule. In 2003, $457 million is available for pass-through expenditures. CMS' projection, at this time, is that all but $7 million will be spent in 2003. However, CMS Administrator Thomas Scully has said that he expects this projection to increase in the final rule, thus triggering a pro-rata reduction beginning in January 2003. The magnitude of this cut remains unclear.

Under the law, about $360 million has been allowed for outlier payments in 2003. The only good news is that drastic payment cuts will mean more services will qualify for an outlier payment. Also, the qualifying threshold is more generous for 2003, being reduced from 3.5 times the APC payment amount to 2.75 times the payment amount. The 50 percent payment rate remains the same.

Under the proposed regulation, payments to all hospitals would increase by 3.5 percent on average. Urban hospitals would see an increase of only 2.5 percent, while rural hospitals would see an increase of 7.6 percent. Payments to smaller hospitals (less than 200 beds) would increase more than 4.3 percent compared to bigger hospitals that will have a payment increase of 2.3 percent or less. Under the new regulation, nonteaching hospitals would have a 5 percent increase in hospital payments compared to 2.0 percent or less for teaching hospitals. The poorer showing for urban, larger, and teaching hospitals is probably due to the changes in payments for drugs and devices.

Final Changes to HIPAA Patient Privacy Rule Issued

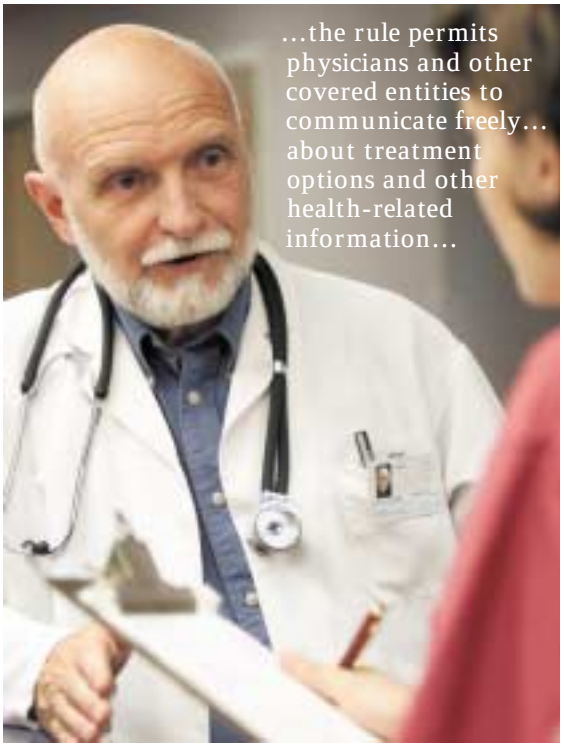
On August 9, the Department of Health and Human Services (HHS) released final changes to the privacy regulations issued under the Health Insurance Portability and Accountability Act (HIPAA) of 1996.

The regulation does not require congressional approval. However, some lawmakers are already expressing concerns over the limited protection provided by this rule and seeing a potential need for further Congressional action to protect patients. The changes were published in the August 14 *Federal Register* and can be downloaded from the web site of HHS Office for Civil Rights at: *http://www.hhs.gov/ocr/hipaa*.

The final regulation, which takes effect April 14, 2003, is the first-ever federal regulation designed to give patients protections over the privacy of their medical records. The rule is intended to protect medical records and other personal health information maintained by certain health care providers, hospitals, health plans, health insurers, and health care clearinghouses. The rule will apply to all patient records kept in electronic form but not those that are on paper. Instead of requiring written consent, the final rule simply specifies that patients must, at some point, be informed of their privacy rights by those who handle their records.

Under the Privacy Rule:

- Patients must give specific authorization before entities covered by this regulation can use or disclose protected information in most nonroutine circumstances, such as releasing information to an employer or for use in marketing activities. Physicians, health plans, and other covered entities would be required to follow the rule's standards for the use and disclosure of personal health information.
- Covered entities generally will need to provide patients with written notice of their privacy practices and patients' privacy rights. The notice will contain information that could be useful to patients choosing a health plan, doctor, or other provider. Patients would generally be asked to sign or otherwise acknowledge receipt of the privacy notice from direct treatment providers.
- Pharmacies, health plans, and other covered entities must first obtain an individual's specific authorization before sending them marketing materials. At the same time, the rule permits physicians and other covered entities to communicate freely with patients about treatment options and other health-related information, including disease-management programs.
- Specifically, improvements to the final rule strengthen the marketing language to make clear that covered entities cannot use business associate agreements to circumvent the rule's marketing prohibition. The improvement explicitly prohibits pharmacies or other covered entities from selling personal medical information to a business that wants to market its products or services under a business associate agreement.
- Patients generally will be able to access their personal medical records and request changes to correct any errors. In addition, patients generally can request an accounting of nonroutine uses and disclosures of their health information.



HHS issued privacy regulations in December 2000 but had to make changes to address serious unintended consequences of the rule that would have interfered with patients' access to quality care. Under the original rule, for example, a pharmacist would have been unable to fill a prescription until the individual signed a privacy notice. Also, under the old rule, a hospital that received patient information from a referring physician would have had to wait to schedule an appointment or procedure until the patient signed a consent form. Under the new rule, neither of these scenarios would be necessary.

Another change in the privacy rule ensures that parents have appropriate access to their children's records by clarifying that state law governs the area of parents and minors.

HHS' privacy regulation is designed to enhance the protections afforded by many existing state laws. Stronger state laws and other federal laws continue to apply, so the federal regulation provides a national base of privacy protections. The standards for covered entities apply whether patients are privately insured, uninsured, or covered under public programs such as Medicare or Medicaid. Business associates of covered entities have an additional year to change written contracts to comply with provisions of the rule.

Concerns Rise Over Group Purchasing Organizations

Recently, the health care industry has raised growing concerns over the efficacy and role of group purchasing organizations (GPOs). This issue was high-

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lighted and addressed in an April 2002 hearing held by the Senate Judiciary Subcommittee on Antitrust, Competition, and Business and Consumer Rights. At that hearing, the General Accounting Office (GAO) announced details of its preliminary report on the cost savings associated with hospitals that are members of GPOs.

GPOs became popular over the past two decades as a way for hospitals to obtain lower prices for goods and services, including drugs and devices. GPOs use the combined purchasing power of their member institutions to negotiate prices from manufacturers that are lower than the prices individual hospitals could negotiate. GPOs also eliminate a number of administrative burdens for hospitals supporting large purchasing departments. For manufacturers, GPOs provide them with access to a large number of hospitals without having to support a sales and marketing staff. (A GPO's total cost administrative fee can be no greater than 3 percent of total sales, as mandated by Congress).

Some members of the Senate subcommittee expressed concern that GPOs may restrict innovation in the health care industry. Because GPOs act as gatekeepers for their hospitals, manufacturers that do not secure contracts with GPOs face large obstacles getting their products into hospitals. Another area of concern discussed at the hearing was that the financial interest of the GPOs themselves and the individuals who operate them are too closely tied to the manufacturers with whom they have contracted. Furthermore, despite regulations governing the amount of administrative fees GPOs can charge or accept from hospitals, GPOs admit that their fees do, at times, exceed the 3 percent limit and that they also have accepted stock from companies in lieu of these payments.

Critics argue that GPOs have an incentive to grant contracts to manufacturers who can produce large financial gains and to block smaller companies from contracts because they are in competition with the firms in which GPOs hold a financial interest. GPOs argue that they use clinical committees to make contracting decisions and the fact that GPOs often return earned profit to member hospitals is evidence that contract decisions are based on cost savings and efficacy for their member hospitals, and not personal gain.

The controversy surrounding GPOs intensified when the GAO announced at the Senate hearing that its preliminary study shows that GPOs do not necessarily negotiate lower prices for hospitals. In a very limited study, the GAO found that, when hospitals used GPOs to purchase pacemakers, they paid prices ranging from 26 percent lower to 39 percent higher than hospitals that did not use GPOs. The GAO found that the range of prices depended on the model being purchased. The GAO plans to conduct a larger study to obtain more definitive answers about GPO effectiveness.

At the April 2002 hearing, the Senate subcommittee requested that the GPO industry self-regulate itself within 90 days or face the possibility of further Congressional action

On July 29, 2002, the Health Industry Group Purchasing Association (HIGPA) released to lawmakers HIGPA's "Code of Conduct Principles" (*www.higpa.org/pressroom/2002/code.asp*). The goal of these new principles is to improve delivery of products and services to health care providers, while also enabling health care institutions to access the latest and most innovative products at the most affordable price.

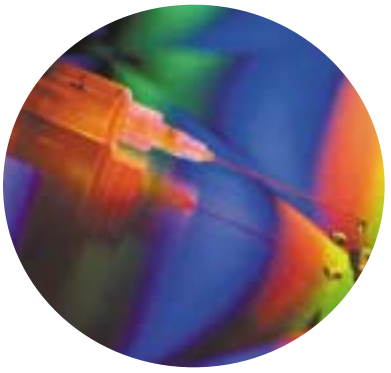
In August 2002, Premier, which negotiates contracts for the purchase of hospital studies for approximately 1,600 hospitals across the country, announced that in addition to implementing HIGPA's self-regulatory principles, they would cap vendor administration fees, limit contract terms with suppliers, and prohibit bundling of products across vendors.

On August 5, the Senate Subcommittee responded to these actions stating that, while progress was made by the industry in general and Premier in particular, additional work remains to be done. ACCC will continue to track development on this issue.

ACCC Urges CMS to Continue Current Reimbursement for Injectables

ACCC, the National Patient Advocate Foundation, the Oncology Nursing Society, and US Oncology called for the withdrawal or significant amendment of the Program Memorandum (PM) to Intermediaries and Carriers (Transmittal No. AB-02-072) issued by the Centers for Medicare and Medicaid Services (CMS) on May 15, 2002. The PM addresses coverage for drugs that are furnished "incident to" a physician's services and are "not usually self-administered by the patient."

CMS announced that it would further clarify this PM before it



took effect August 1. CMS has yet to issue such a clarification. ACCC continues to monitor developments and is concerned that some carriers may drop coverage of some cancer drugs if a clarification is not forthcoming.

In its letter to CMS Administrator Thomas A. Scully, ACCC recommended that CMS take the following actions to ensure that facilities that provide quality cancer care are reimbursed:

- Continue current Medicare reimbursement for injectable drugs consistent with current statutory language and the BIPA language of 2000
- Remove from coverage decisions presumptions about treatment frequency that are not based upon reliable data and do not reflect current

PHOTOGRAPH BY EYEWIRE

cancer treatment, including but not limited to the PM's distinction between subcutaneous and intramuscular methods of drug administration

- Base definitions of "usually" on the entirety of the Medicare population, without excluding a segment of this population for the sole reason that they are in fact unable to self-administer drugs
- Apply a standard of coverage consistent with the intent of Congress that all Medicare beneficiaries have equal access to reimbursement for care
- Place the evidentiary burden about how a drug is administered on CMS before denying coverage of self-administered drugs, which would be consistent with congressional intent.

Due to the complexities of this issue, ACCC believes that patients and health care practitioners should be able to submit public comments on future coverage recommendations by the agency.

Over the next 30 years, the number of patients with cancer over 65 years of age is expected to double.

Cancer Incidence to Double by 2050

An annual update on cancer incidence and trends in the U.S. shows that, while cancer death rates and cancer incidence rates have stabilized, demographic changes over the next 50 years are expected to significantly increase the number of cancer patients nationwide.

The American Cancer Society, the National Cancer Institute, the North American Association of Central Cancer Registries, the National Institute on Aging, and the Centers for Disease Control and Prevention, including the National Center for Health Statistics, collaborated to provide the annual update on cancer occurrence and trends in the United States. The current report, published in May 2002, contains a special feature that focuses on the implications of age and aging on the U.S. cancer burden.[1]

The report recognizes that projecting cancer rates over 50 years is a difficult and complicated task. However, if current rates are applied to the next 50 years, increases in the average life span and the aging of the baby boom population would result in a doubling of cancer incidence from 1.3 million in 2000 to 2.6 million in 2050. This dramatic increase in cancer incidence is expected to occur even though progress in treatment and detection has resulted in an increased number of early diagnoses and a corresponding drop in cancer death rates. Over the next 30 years, the number of patients with cancer over 65 years of age is expected to double, raising important implications for the nation and policy leaders as they prepare to care for these patients within the Medicare system.

According to the report, the median age at which cancer is diagnosed is 68. Survival rates were more dependent on the type of cancer and its progression than on the patient's age, and age does not appreciably affect survival rates for many cancer sites. As the population grows older and the number of individuals over 65 increases, the number of cancer survivors will also increase. This group has unique needs and risks for cancer, but they remain underrepresented in clinical trials. The report found that, despite efforts currently underway to improve participation in clinical trials, a need remains to specifically target older patients.

On the positive side, overall cancer death rates decreased across all age groups and in both men and women from 1993 through 1999, while cancer incidence rates stabilized from 1995 through 1999. Age-specific trends varied by disease site, sex, and race.

The report insists that, as the population of cancer patients and survivors continues to grow, government policy must continue to support and fund the medical infrastructure necessary to care for these individuals. In 2001 alone, the overall cost of cancer services is estimated to be $156.7 billion. Six areas that need to be better addressed include 1) prevention and early detection, 2) social support, 3) treatment, 4) general medical care, 5) public and private partnerships, and 6) surveillance. The report specifically states a need for medical professionals, especially oncology nurses and experts in palliative care, and more extensive data collection on cancer incidence, treatment, and survivorship.

ACCC continues to work on numerous fronts to ensure that government policy supports appropriate cancer treatment and recognizes the cost of providing such care.

[1]*Edwards BK, Howe HL, Ries LAG, et al. Annual report to the nation on the status of cancer, 1973-1999, featuring implications of age and aging on the US cancer burden.* Cancer. *May 15, 2002;94(10):2766-2792.*