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Advisory

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HEALTH CARE

HCFA Issues Long-Awaited Proposal on Covering New Technologies

After a protracted debate, the Health Care Financing Administration (HCFA) last month proposed tentative criteria that it would use to determine whether new medical technologies and innovations are worthy of Medicare coverage. For years, applications for Medicare coverage of a new device or technology languished behind closed regulatory doors.

When applications were ultimately turned down and new products or services were denied coverage, applicants were left without any understanding of the rationale behind the rejection. HCFA's recent issuance is its long-awaited attempt to shed new light on its decision-making process.

The openness campaign has to date also included a HCFA promise to respond to requests for coverage within a 90-day period and to provide all information about individual coverage reviews on the World Wide Web. In addition, HCFA has convened the Medicare Coverage Advisory Committee (MCAC), a blue-ribbon panel established to advise the agency on individual coverage requests. Because the MCAC is advisory in nature, HCFA is not required to follow any of its recommendations. The release of these proposed criteria, however, remains a significant development because it allows both HCFA and the MCAC to utilize the same tools in evaluating requests for coverage.

The new tentative criteria come after previous attempts to establish national coverage criteria were shelved in response to industry and Congressional concerns about the proposed role of cost-effectiveness evaluations in making coverage decisions. The new proposal does nothing to dispel those concerns. In light of the issue's political volatility, HCFA published a "notice of intent" to publish a proposed rule (NOI). See 65 Fed. Reg. 31,124 (May 16, 2000). The NOI is also available at www.hcfa.gov/quality/8b2-b.htm. HCFA will take comments on the NOI for 30 days (until June 15, 2000), then issue a proposed rule that will be subject to typical notice and comment procedures.

Although HCFA acknowledges the need for Medicare beneficiaries to receive timely and expanded access to new technology, the proposed coverage criteria, which will apply to national and local coverage decisions, juxtaposed with the existing coverage process (widely derided by critics as too secretive, slow and unpredictable), promises anything but.

By statute, Medicare is a defined benefit program, which means that Medicare may provide beneficiaries only those benefits that fit into one of the fifty-or-so benefit categories described in the Social Security Act (the Act). In addition, Medicare is prohibited from paying for items and services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to

improve the functioning of a malformed body member.” “Reasonable and necessary” are not defined in the Act and the determination of reasonable and necessary has generally been left to the local contractors that administer the Medicare program.

Historically, HCFA has issued few national coverage decisions, leaving decisions about what technologies are worthy of coverage to be made on a local level by contractors. Still, the medical products industry, the medical profession and beneficiaries have expressed a strong desire to date to understand the criteria by which HCFA makes its coverage decisions. The NOI reflects HCFA’s attempt to explain how it will determine whether an item or service is “reasonable and necessary” and thus eligible for coverage. Medicare’s coverage decisions are also closely watched, and often followed, by private insurers. Consequently, the stakes for medical device and technology companies that apply for Medicare coverage decision are extremely high.

In the NOI, HCFA proposes two criteria that will be applied when it makes a national coverage decision or when its local contractors make local coverage decisions: (1) does the item or service provide a medical benefit, and (2) does the item or service add value to the Medicare population. Assuming that a medical benefit exists, HCFA would then consider whether a Medicare-covered alternative already exists and, if so, whether it is more or less beneficial and costly than the new item or service. An item or service that is substantially more beneficial than a Medicare-covered alternative would be covered; an item or service that is substantially less beneficial would not be covered; and an item or service that is equivalent to a Medicare-covered alternative would be covered only if it would result in equivalent or lower total costs for the Medicare population.

HCFA said it would measure medical benefit and added value by clinical scientific evidence, but would seek comments on the proper evidentiary

standard to be used, as well as the proper interpretation of the terms “medical benefit” and “added value.” For example, HCFA is asking for suggestions on how to determine whether a new technology is of the “same clinical modality” as an existing Medicare-covered benefit or whether it is “substitutable”—two determinations that would have to be made before HCFA could conclude that the new technology provides added value.

In proposing its own evaluation of the scientific evidence that would support clinical effectiveness, HCFA surprisingly gives no recognition to the safety and efficacy evaluation that the Food and Drug Administration (FDA) is statutorily required to perform before a new medical device may be marketed. In addition, HCFA said it would not cover FDA-regulated products if they are not lawfully marketed—a position that appears to rescind previously adopted criteria for covering certain investigational use only (IUO) medical devices. According to these criteria—articulated in a 1995 interagency agreement between HCFA and the FDA, and HCFA regulations—FDA-designated “non-experimental/investigational” devices are subject to the same process and criteria used in making coverage decisions for legally marketed devices. Payment would be limited, however, to the amount that would have been paid for a currently used FDA-approved device for the same medical purpose.

Medical community and industry response to the NOI has been swift, and, for the most part scathing. Several industry groups have already requested an extension of the June 15 comment deadline. Chief among critics’ concerns are the rigidity of HCFA’s proposed approach, the inclusion of cost-effectiveness criteria that go beyond HCFA’s statutory power to make coverage decisions, and the likely additional delay in providing new medical technology to the Medicare population.

Supreme Court Rules that Medicare Providers are Subject to the Federal Bribery Law

Federal health care fraud prosecutors acquired important new tools last month when the Supreme Court ruled that Medicare providers receive federal “benefits” and are covered by the federal bribery statute (18 U.S.C. § 666). *Fischer v. United States* (No. 99-116, May 15, 2000). The federal bribery statute carries with it the ancillary enforcement tools of asset forfeiture, injunctive relief, and civil investigative demands. Prosecutors may therefore turn to the bribery statute as the enforcement weapon of choice.

In *Fischer*, the Court upheld the multiple count conviction of Jeffrey Fischer, who was President and part-owner of Quality Medial Consultants, Inc. (QMC). In 1993, Fischer arranged for QMC to obtain a \$1.2 million loan from West Volusia Hospital Authority (WVHA). It appears that the purpose of the loan was to pay for operational expenses of QMC, a company that performed billing audits for health care providers. Fischer pledged QMC’s accounts receivable as security for the loan, along with a \$1 million letter of credit from a foreign bank. However, it was subsequently discovered that the loan funds were used to pay off existing creditors and raise the salaries of its five owner-employees, including Fischer. The loan proceeds were also used to pay for a \$10,000 “kickback” to WVHA’s Chief Financial Officer, paid indirectly through the CFO’s mother and variously described as a “consulting fee” or a “loan-origination fee.” When QMC

defaulted on its obligations, WVMA found that it did not have a valid security interest because QMC had pledged the receivables to another QMC creditor.

The federal bribery statute criminalizes, among other offenses, offering a bribe to a person connected to an organization which receives “benefits in excess of \$10,000 [annually] under a Federal program involving a grant, contract, subsidy, loan, guarantee, insurance, or other form of Federal assistance.” Fischer argued that Medicare beneficiaries received Medicare “benefits,” not providers such as WVHA, which was paid for providing the services. In a 7-2 decision, the Court held that the receipt of Medicare funds by WVHA was more than a simple commercial transaction, which wouldn’t qualify as federal “benefits.” Rather, the Court said, “The structure and operation of the Medicare program reveal a comprehensive federal assistance enterprise aimed at ensuring the availability of quality health care for the broader community.”

While the Court found that WVHA received federal benefits, it rejected the government’s argument that any receipt of federal funds constituted “benefits,” noting that the government’s argument would turn any act of bribery or fraud into a federal offense. Whether a payment is a “benefit,” according to the Court, requires an examination of “the program’s structure, operation, and purpose. The answer could depend, as it does here, on whether the recipient’s own operations are one of the reasons for maintaining the program. Health care organizations participating in the Medicare program satisfy this standard.”

The dissent described this decision as far-reaching. Among the potentially far-reaching implications are whether providers will now be viewed as subject to the numerous federal contracting rules. On the positive side, courts have granted constitutionally protected rights to parties receiving federal benefits that health care providers heretofore have been unable to win because they were not viewed as recipients of federal benefits.

Although there could be situations where conduct could be charged under either the federal bribery statute or the Anti-Kickback Statute, the bribe in *Fischer* did not appear to implicate the Anti-Kickback Statute. Consequently, the Court did not discuss the interplay, if any, between the two statutes nor the availability of the safe harbors contained in the Anti-Kickback Statute.

White House Unveils Internet Pharmacy Legislation

Last month, the White House sent to Congress a bill that would regulate Internet pharmacies in order to, in its own words, “protect consumers.” According to Department of Health and Human Services (HHS) Secretary Donna Shalala, the goal of the legislation is to effectively protect the public health by filling in the gaps in federal and state authority without hindering the potential benefits the Internet offers. The Internet Prescription Drug Sales Act of 2000 would amend the Federal Food, Drug, and Cosmetic Act (FDCA) to require Internet pharmacies, both foreign and domestic, to be licensed in every state in which they operate or to which they deliver prescription drugs, and comply with all applicable federal and state laws that govern the practice of pharmacy. If the Internet pharmacy simply offers prescription drugs generally, then the legislation requires that the pharmacy be licensed in all 50 states.

Under the bill, Internet pharmacies would be required to provide to the Secretary and appropriate state boards of pharmacy, 30 days prior to creating the Web site, a notification about the information required to be posted on the site and assurances of compliance with the law. The online pharmacy would then have to post on its Web site a declaration of compliance with this requirement.

The sites would also have to post the address of the online pharmacy, the name, credentials, and telephone number of the pharmacist in charge, the list of states in which the pharmacy is licensed to practice, and a statement that the pharmacy will only dispense drugs to patients with a valid prescription living in states in which the pharmacy maintains licenses.

The Clinton bill would also allow HHS to designate other non-profit organizations or agencies to verify licensing information for Internet pharmacies. Although the legislation does not specify who will have the authority for implementing this certification program, the Clinton budget proposal allocates \$10 million to the Food and Drug Administration to combat illegal Internet drug sales. The bill would also give the Attorney General or the Attorney General’s designee, civil and criminal subpoena authority over online pharmacy Web sites and amend the FDCA to create civil fines of up to \$500,000 for Internet pharmacies that violate licensure requirements. Under the legislation, states would be allowed to seek federal injunctive relief and bring civil actions against Internet pharmacies that violate the standards.

Despite these overtures from the Administration, some Members of Congress are voicing increasing concerns about the federal enforcement climate, which they claim is too lax. Among the chief critics is House Commerce Committee Chairman Tom Bliley (R-VA), who late last month held a hearing of his Subcommittee on Oversight and Investigations in which he delivered his strongest criticism to date of the Administration’s effort to curtail illegal drug sales over the Internet. “While the President has talked a big game about Internet pharmacies, not one arrest or conviction related to Internet prescription drug sales has taken place since [the problem surfaced] last year,” he said. Echoing Bliley’s criticism, Reps. Fred Upton (R-MI) and Ron Klink (D-PA) also questioned the panel of Administra-

tion officials about what they said was a lackluster enforcement record.

“We’ve all heard the stories of people being able to obtain drugs online posing as cats, dogs, dead people, young children, or as patients with contraindicated conditions. What we don’t hear is how the federal government is aggressively attacking this problem,” Klink said. Administration officials, representing both the FDA and the Department of Justice, testified that obtaining a conviction of those involved in Web crimes is much more difficult than it seems.

The Senate Health, Education, Labor and Pensions Committee (HELP) held two hearings this spring designed to edu-

cate members of Congress about the mechanics of online pharmacies and determine the scope and nature of the problems presented by the sale of prescription drugs over the Internet. The hearing, held in April, focused largely on consumer protection issues. Several witnesses emphasized that existing state and federal law can only protect individuals on a limited basis because consumers are able to purchase drugs online without consulting a physician, having a prescription, or receiving any assurances about the quality of the drugs being sold. Other witnesses advocated a “wait and see” approach in response to suggestions for new state and federal legislation, noting that the appropriate laws may exist but

are not effective because enforcement authorities lack the funding and technology to carry them out. Several witnesses opposed federal regulation altogether, under the theory that regulation of pharmacy is a state responsibility and should remain so. The hearings also addressed the issue of foreign-based web sites, which typically evade U.S. law and federal regulation.

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