

HCFA HOLDS BRIEFING ON OUTPATIENT DRUG PRESCRIPTION COVERAGE

Drug Coverage

It has not yet been decided how the Health Care Financing Administration (HCFA) and the Secretary of Health and Human Services (HHS) will make drug coverage decisions under the outpatient prescription drug amendment to the Medicare Catastrophic Coverage Act, according to speakers at a recent public briefing in Washington, DC.

Kathleen Buto, acting director for the Bureau of Eligibility, Reimbursement and Coverage, said that the "current position is to recognize all three drug compendia sources" recommended as references for the Secretary of HHS in the legislative intent of the catastrophic act (the *U.S. Pharmacopoeia Dispensing Information*, the *AMA's Drug Evaluations*, and the *American Hospital Formulary Service Drug Information*). However, Buto said that the Agency is "open to recommendations on additional compendia, as well as criticism of any of the three recommended compendia. By no means do we regard them as the last word," she explained. She warned that HCFA "could still come up with its own standards," noting that the legislation permits the exclusion of "specific drugs, uses of drugs, or classes of drugs if the Secretary determines that they are not safe and effective."

While HCFA will not be taking a "cookbook approach" in determining what drugs will be covered under the amendment, the only firm decision by HCFA to date is that "all labeled uses for all FDA-approved drugs will automatically be covered," Buto said. Other coverage decisions are "open to discussion."

HCFA is "aware that some carriers are denying payment for off-label use," and that Medicare intermediaries do not follow a uniform policy with regard to off-label usage. The general thinking is that off-label uses are covered, Buto said, but the extent of coverage is "left to the discretion of carriers." However, she believes that Congress has explicitly recognized off-label uses through its citing of three compendia that acknowledge off-label indications.

Home IV Drug Therapy

HCFA has had a great deal of "difficulty in compiling a list of eligible home IV drugs," said Robert Wren, director, the Office of Coverage Policy. The Secretary of HHS cannot simply reference compendia, but is required by statute to compile a list of covered drugs and uses for antibiotics and non-antibiotics, including anti-infective agents, antineoplastics, pain management agents, and other cancer-related drugs.

Courses of home IV therapy must be "furnished by a qualified home IV provider," Wren said, and "the plan of care must be reviewed and established by the patient's physician." Home IV therapy will be "subject to PRO review at least until January 1995." Moreover, the law precludes payment when the referring physician has a significant financial or ownership interest in the home IV company. Wren said "significant" interest has the same definition as in the home health agency regulations; that is, physicians who receive five percent or more of the capital profits, receive significant compensation from the provider (more than five percent of operating costs), or serve as an executive or a board member for the company.

Home IV therapy providers must meet HCFA's conditions of participation, including the direct provision of nursing and pharmacy services, recordkeeping that is in accordance with state laws, patient selection criteria, written protocols, etc. The provider must closely coordinate patient treatment with the referring physician, including an initial consultation and physician recertification of treatment regimens.

Payment will consist of the lower of the actual charge or a per diem fee schedule. The fee schedule is currently being calculated by HCFA and will weight such aspects of home IV therapy as nurse visits, delivery fees, equipment, etc.

Peer Review

State-based Peer Review Organizations (PROs) will perform both prior authorization for inpatients and retrospective review of claims. Preauthorization may be requested by the prescribing physician, the hospital, or a home IV therapy provider. HCFA will complete the review "within one working day of the request/the receipt of the information needed to perform the review," said Pat Booth, director, Division

of Review Programs. In the case of home IV therapy, the PRO will complete its review within one working day of the initiation of therapy, Booth said.

Drug Utilization Review

Conceptually, the drug utilization review program will be conducted in two stages: prepayment (at the point of sale) and postpayment, according to Buto. The amount of utilization information communicated at the point of sale will "obviously have to be limited," Buto said, noting the expense of providing such information. The primary focus of prepayment review will be to identify potential adverse drug interactions. Postpayment review will attempt to identify substandard care and inappropriate prescribing practices. At this point in time, however, Buto said HCFA has not yet determined what criteria will be used. "We must feel our way carefully," she said, "because of the medical necessity questions involved in drug utilization review."

At the present time, the way the program is structured, off-label uses cannot be identified at point of sale, because prescriptions will not be changed to include diagnostic information. However, retrospective reviews will have data that cross-match diagnoses and prescriptions. According to Buto, retrospective DUR will have to focus on outliers, at least at first, because of the number of claims that will be processed through the program (an estimated 700 million during the first year of the outpatient drug prescription benefit).

Proposed Regulations

There are eight sets of proposed regulations to be published by HCFA in the *Federal Register* this year. C. Ross Anthony, Ph.D., associate administrator for program development, said that most of the following regulations will be published in June:

- Prescription Drug Benefit Copayments
- Coverage of Outpatient Prescription Drugs
- Drug Payment Methodology
- Coverage of Home IV Therapy Services
- Home IV Drug Provider Conditions of Participation
- Home IV Drug Therapy Fee Schedule
- List of Covered Drugs for Home IV Therapy
- Agreements for Participating Pharmacies. ■