Chapter 5

QUALITY ASSURANCE IN HOME DRUG INFUSION THERAPY

Contents

Boxes

Tables

Chapter 5

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Overview

Introduction

As described in previous chapters, home drug infusion therapy (HDIT) is a high-technology, invasive service that can pose considerable risk to patients. Complications of therapy are potentially more serious in the home than in the hospital, because health personnel are not be immediately available to recognize and treat them. HDIT is further complicated in that it requires the coordination of multiple services (medical, pharmacy, nursing, laboratory, and supply) that are often provided by separate entities. If Medicare were to provide coverage for HDIT services, it would want to implement some measures to protect beneficiaries from inappropriate and substandard care. This chapter examines what measures might be possible.

The chapter first discusses key issues in HDIT quality assurance at the provider level and reviews existing standards for HDIT Next, it reviews past and present Federal quality assurance efforts in home care generally and in home infusion therapy specifically. Finally, the chapter examines the potential Federal role in assuring the quality of HDIT services provided to Medicare beneficiaries.[1] In this last task, the chapter reviews and critiques some of the requirements that might have been imposed upon providers in the wake of the Medicare Catastrophic Coverage Act of 1988 (MCCA)[2] (which was repealed before proposed regulations could be made final). It also examines potential roles for Medicine peer review organizations (PROS).

Summary of Conclusions

- The complicated and invasive nature of HDIT, the limited knowledge about the safety and effectiveness of some therapies in the home setting, and the comparatively frail health status of some Medicare beneficiaries warrant rigorous Federal oversight of HDIT quality assurance at least at the outset of a Medicare benefit, if not on a continuing basis.
- The degree to which Medicare can rely on State licensure and certification as a means of assuring HDIT quality is extremely limited. State regulation of HDIT providers is still absent in most States and inconsistent among States where it does exist. Federal policy could help to focus and standardize State HDIT regulatory efforts.
- The most consistent measures of HDIT provider quality currently available are standards published by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) and the National League for Nursing's Community Health Accreditation Program (NLN/CHAP). However, accreditation through these channels can be costly to obtain, and many existing providers have not sought it. Thus, Medicare should rely on State agencies, acting under explicit and consistent guidelines, to determine initial and continuing compliance with any conditions of participation (COPS) that Medicare develops. This will undoubtedly mean that some providers will need to seek multiple certification (e.g., compliance with JCAHO standards for private insurer reimbursement, State licensure requirements for facility operation, and an additional set of COPS for Medicare reimbursement), which many will find burdensome. Eventually, JCAHO- and NLN/CHAP-accredited HDIT providers could be granted "deemed status" if accreditation standards were commensurate with Medicare's COPS.
- Individual case review at some level is critical to assuring safety, appropriateness, and consistency in HDIT PROS could conduct at least retrospective review of a random sample of HDIT cases. Prior authorization by PROS for 100 percent of HDIT claims would be administratively costly and may not be necessary. As an

[1] OTA defines "quality of health care" as the evaluation of the performance of health care providers according to the degree to which the process of care increases the probability of outcomes desired by patients and reduces the probability of undesired outcomes, given the state of medical knowledge. Which elements of patient outcomes predominate depends on the patient condition (363).

[2] Public Law 100-360.

alternative, prior authorization, performed by either PROS or fiscal intermediaries (FIs),[3] could be reserved for certain therapies or certain patients who are determined to be at increased risk.

- Physician involvement is key to safe and effective delivery of HDIT services. To ensure appropriate physician oversight in the event of a Medicare benefit, HCFA could develop specific requirements or incentives and could charge PROS with reviewing compliance at the case level.
- Although many patient care services may be performed under contract rather than directly by an HDIT provider, certain functions should remain the primary responsibility of the provider. These functions include: initial patient assessment; quality assurance; maintaining clinical records; periodic drug regimen review; coordinating all HDIT services; guaranteeing 24-hour a day, 7-day a week availability of emergency services; and serving as the initial point of contact for patients in the event of questions, concerns, requests for supplies, and any emergencies.
- Because many of these functions require the expertise of a professional nurse well-versed in HDIT practice, an HDIT provider should employ directly at least one registered nurse (RN) whose training and prior experience qualify him or her to assume these responsibilities. In addition, an HDIT provider should have a qualified pharmacist either on staff or hired on a consulting basis.
- In the event of an HDIT benefit, Federal policies could help both patients and providers protect themselves from adverse outcomes and potential legal consequences of those outcomes. For example, providers could be required to ensure that patients understood their responsibilities for HDIT and consented to them in writing. Providers could also be required to give patients a single telephone number they can call in the event of any complication or emergency and be assured an immediate personal response.

Quality Issues in HDIT

Only the provider can ensure that good quality HDIT is provided on a day-to-day basis for each individual patient. As discussed later, many external standards are aimed at ensuring that providers have internal procedures for addressing quality-of-care issues. This section discusses some of the areas where provider procedures for quality assurance are especially critical.

Patient Screening and Assessment

Appropriate patient screening is the first and most important step in HDIT quality assurance the provider takes. For Medicare beneficiaries, who are more likely than other individuals to have fragile health conditions and limited functional capacity, careful assessment is crucial. As discussed in chapter 3, screening requires a thorough assessment of medical and nonmedical characteristics that render a patient appropriate or inappropriate for HDIT. These characteristics include stability of the patient's medical condition, willingness of the patient to undergo home therapy, knowledge and ability of patient (or caregiver) to perform self-care, equipment used, type and toxicity of drug, and environmental characteristics of the home setting (25).

But a thorough initial assessment also requires that the provider consider what types of services it is capable of delivering in a safe and efficient manner. If a patient requires services that a provider cannot deliver directly, the provider must either refer the patient elsewhere or make contractual arrangements to provide those services. The complicated nature of HDIT and the variety of factors that can influence ultimate patient outcome demand that patient screening be a multidisciplinary effort involving physicians, nurses, pharmacists, and other health professionals as necessary (e.g., a social worker) (131,270).

Patient and Family Caregiver[4] Training

Home care in general poses challenges for quality assurance because many patient care factors are not under the direct control of the provider. Procedures as critical as catheter flushing and intravenous (IV)

3 Medicare fiscal intermediaries include Part B carriers and Part A intermediaries who contract with the Health Care Financing Administration to process claims and perform other administrative tasks associated with the Medicare program.

4 "Family caregiver" refers hereto a family member or friend who assists the patient in self-care responsibilities on an unpaid basis. It does not include paid caregivers such as home health aides, for whose actions the employing agency is legally responsible.

drug administration are often performed by the patient without any supervision. A broad range of factors can affect the degree to which a patient is able or willing to comply with self-care instructions (table 5-l).

Providers exercise control over the quality of self-care techniques through comprehensive training of the patient and family caregiver. These techniques are not trivial to learn. In a recent survey, 92 percent of primary care physicians felt that patients and family members could be taught general self-care, but only 47 percent felt their patients could be taught the complex level of self-care required for HDIT (342). Medicare beneficiaries with fictional or cognitive limitations may find it especially difficult to perform certain procedures safely (134). In these cases, additional skilled nursing services may be necessary to ensure good-quality care (134) (see ch. 3).

Providers can undertake some specific measures to assure the quality of patient education. These include:

- *The use of standardized teaching and reference materials (210,296).* Patient instruction manuals should be written on a level that patients can understand (90,240,296).
- *Continuity in training with equipment and supplies. If* a patient is trained on one infusion pump and sent home with another, for example, he or she might not know how to start or stop the pump (390).
- *Continuity among instructors in patient instruction (e.g., dressing* changes and aseptic technique). Teaching different ways of undertaking self-care techniques can cause confusion, leading to poor performance of self-care tasks (210).
- *Beginning patient training before hospital discharge* (for patients whose therapy is initiated in the hospital) (240,296,364). Ideally, to ensure that the patient can transfer what he or she has learned to the home setting, a nurse or pharmacist would visit the home to observe that patient or family caregiver administer the frost home dose (240,364).

Patient Rights and Responsibilities

Existing standards for HDIT providers all require that the primary provider assume legal responsibility for the quality of any services provided to its patients on a contractual basis. They also require that the provider have written policies describing what specific services it is capable of providing and under what types of arrangements it provides them (178, 230,237). Most standards require nurses or other health personnel to document that patient training in self-care techniques has been completed satisfactorily (42,178,237).

The nurse's documentation does not itself constitute a patient's assertion of shared risk-i.e., that the patient understands his or her responsibility for self-care to reduce the risk of adverse health events. To effect such an assertion, the HDITprovider could

Table 5-l-Factors Affecting Compliance in Home Intravenous (IV) Antibiotic Therapy Patients

Physiologlcal factors
Age
Physical disabilities
Arthritis
Paralysis
Amputation
Decreased or poor vision
Cast requiring crutches, walker, or wheelchair
Neuromuscular dysfunction, multiple sclerosis, Parkinson's disease
Neuropathy secondary to diabetes mellitus
Diagnosis: duration and severity of disease
Dosing frequency and length of therapy
Pain
Lack of fine motor skills
Decreased strength and dexterity
Side effects of medications
Poor venous access requiring central line placement
Psychosocial factors
Education
Lack of care partner
Desire to go home
External locus of control
Socioeconomic status
Home environment
Community resources
Storage/refrigeration space
Fear/isolation
Decreased socialization (especially with multiple IV antibiotics and frequent dosing)
Cost/Insurance coverage
Sleep deprivation from frequent dosing
Other family responsibilities (e.g., mother with small children, ill spouse or parent, work, school)
Altered body image due to heparin lock/central line
Denial of diagnosis requiring IV antibiotic therapy
Inaccessible floor plan in home
Nursing/rnaditxl support
***Lack* of adequate patient education program**
Unclear understanding of rationale of therapy
Inaccessibility to nursing personnel on a 24-hour basis
Poor home followup by home care agency

SOURCE: Adapted from M.S. Neiderpruem, "Factors Affecting Compliance in the Home IV Antibiotic Therapy Client," *Journal of /intravenous Nursing* 12(3):136-142, May/June 1989.

be required to detail in writing those aspects of care for which the patient is responsible and have the patient acknowledge that responsibility by reading and signing an agreement.

Cost to the patient has been cited as a factor that can affect patient compliance in HDIT (240) (see table 5-l). To minimize patient concern about unexpected costs associated with therapy, providers could be required to inform patients before therapy starts about which specific items and services are covered, which are not, and what the patient's cost share will be.

Clinical Considerations

One of the greatest risks of infusion therapy is risk of secondary infection. Strategies for minimizing this risk in the home include:

- careful aseptic preparation of drugs and fluids to be infused;
- using the aseptic technique (see ch. 3, box 3-A) each time the line is accessed or the catheter exit site is exposed (e.g., during drug administration, dressing changes, catheter care);
- minimizing the number of times the patient's catheter, the administration set, or the container of infusate are exposed or changed (since each exposure increases the potential for contamination);
- periodically replacing devices or parts of the equipment that are subject to contamination (e.g., peripheral catheters, administration sets, falters, injection caps); and
- utilizing in-line antimicrobial filters (unless their use is contraindicated-see ch. 3) to eliminate possible contaminants from the infusate before it enters the vascular system.

To ensure that all these steps are followed, all patients, family caregivers, and patient care staff must be instructed in and be able to demonstrate the requisite techniques and precautionary measures.

Although patients may be expected to perform routine tasks associated with their therapy, they must have access to emergency assistance should any complications arise. The invasive nature and potential risks of HDIT demand that emergency services be available on a 24-hour a day, 7-day a week basis (174,178,230,240,248). This means that infusion provider staff (e.g., nurses and pharmacists) and the patient's physician must always be within reach by phone and able, if necessary, to see the patient personally or deliver emergency supplies immediately. To avoid patient confusion, providers may give the patient a single number to call in order to report any kind of emergency or problem. The staff person who answers that call can then immediately contact the appropriate staff, contract employees, or, if necessary, the physician, to respond to the situation.

Staff Qualifications

Regardless of how well organized and coordinated the services of an HDIT provider are, the quality of patient care will suffer if the individual staff members who provide those services are not adequately qualified to do so. HDIT involves a variety of skilled techniques with which the average nurse and pharmacist are not likely to be familiar (see table 5-2).

As discussed in chapter 3, formal training and certification in certain areas of specialty practice may be reasonably good indicators of staff capability and experience, but they do not guarantee proficiency in any given skill area. For example, a certified advanced practice RN may have difficulty inserting traditional peripheral catheters, while a basic RN who has pursued special training may be proficient in a technique as advanced as PICC (peripherally inserted central catheter) line placement. State pharmacy regulations in some cases act as indirect controls over general pharmacist qualifications, but they rarely offer a direct mechanism for assessing specific proficiencies (63). The burden therefore falls upon the employer to determine staff proficiency through employment screens, educational requirements, and on-the-job training in specific techniques.

In addition to knowing certain requisite techniques, skilled staff must be receptive and adaptive to the constant stream of new technologies that quickly become state-of-the-art in HDIT Recent technological advancements in home care have led home health agencies HHAs) and other home care providers to seek more highly skilled staff and to offer more in-service training in the use of new techniques and equipment (12,182). A 1987 study of 287 HHAs, for example, found that venipuncture, physical assessment, patient teaching, and IV therapy management skills were among the most highly ranked qualifications sought in agency nursing staff

Table 5-2—Examples of Home Infusion Nurse and Pharmacist Skills[a]

Nurse skills
• Traditional peripheral catheter insertion
• Peripherally inserted central catheter ("PICC line") placement
• Catheter maintenance and repair
• Familiarity with equipment and supplies used in drug administration
• Awareness of potential side effects of specific therapeutic regimens
• Ability to recognize and treat infusion therapy-related complications
• Ability to practice autonomously
• Patient training
• Ability to communicate effectively with the patient, pharmacist, and other staff
• Ability to assess infusion-associated emergencies and undertake appropriate steps
Pharmacist skills
• Compounding drugs for infusion
. Thorough knowledge of infusion drug stability and compatibility
• Thorough knowledge of potential infusion drug side effects
. Knowledge of therapeutic alternatives in the event of complications
. Familiarity with equipment and supplies used in drug administration
• Ability to communicate effectively with physicians, nurses, and other staff
. Ability to communicate effectively with patients directly
. Ability to assess infusion-associated emergencies and undertake appropriate steps

[a]Skills typically associated with home infusion therapy provision. Not all home infusion nurses and pharmacists need to be proficient in all skills listed. Larger home infusion providers maydivideresponsibilities between staff who specialize in one or more skill.

SOURCE: Office of Technology Assessment, 1992.

(182). Similarly, pharmacists must be up to date on newly emerging home therapies in order to advise physicians, nurses, and patients of therapeutic risks and alternatives.

The HDIT provider can help to maintain the proficiency of its staff by encouraging, mandating, and even providing ongoing education in new therapies, technologies, and techniques. The Federal Government can help ensure staff quality by requiring providers to offeror facilitate staff access to such training and by requiring that providers evaluate and document staff proficiency on a regular basis. A precedent under Medicare is the requirement that certified HHAs provide in-service education and competency evaluations for home health aides (SSA sec. 1891(a)(3)). Regulations issued by HCFA specify requirements for the curricular content of home health aide training programs (54 F.R. 155).

The Role of the Physician

The referring physician is the critical gatekeeper in HDIT. It is the physician who is responsible for prescribing the therapy, ordering all services provided to a patient, and consulting with HDIT staff in the event of any complications (121,178,237). The patient's physician must also be readily available for both emergency and routine consultation (e.g., to discuss lab results or changes to the therapy).

Because the physician bears responsibility for the plan of care, safe and effective delivery of HDIT services by the provider depends on the physician's understanding of the services and willingness to participate in care. However, the Office of Technology Assessment's (OTA's) discussions with physicians and HDIT providers suggest that physicians vary in their understanding of HDIT services and their willingness to play an active role in patient monitoring. Ideally, physician abilities should include home health care patient assessment skills; knowledge of home care therapies and technologies; knowledge of when to recommend specific nonphysician home health services; ability to play an active and effective role in home health care; and ability to evaluate the efficacy of home health care services and contribute to home health care quality assurance efforts (12).

Legal, financial, and professional concerns can impede physician involvement in home care (12). Physicians cite fear of malpractice, lack of compensation, and lack of faith in the quality and supervision of home care personnel as deterrents to referring their patients to home care (203,342). To date, legal concerns of physicians regarding home care have been largely theoretical, since few if any legal actions have been taken by home patients (12). Because HDIT services are generally delivered by licensed nonphysician health professionals who, along with their employers, assume legal liability for the care they provide, a physician's legal risks from referring a patient to HDIT may be no greater than those associated with referral to an acute-care hospital (248). However, the potential for physician liability-particularly where high-technology home care is involved-continues to be of concern, particularly where the physician feels he or she has little control over the conduct of the patient care received in the home (12,108,248). In a recent national survey of 1,100 primary care physicians,

over 60 percent felt there were significant differences in quality of care offered by different HDIT providers (342). Sixty-four percent of the physicians surveyed preferred providers who could offer both HDIT and general, comprehensive home health care services (342).

In the event of an HDIT benefit under Medicare, several strategies would be available to encourage adequate physician involvement in HDIT. For example:

- Regulations could require a minimum frequency of physician-patient and physician-provider contact. The appropriate frequency would probably vary depending on the type of therapy and the patient's overall medical condition.
- Medicare could provide financial reimbursement for the time physicians spend monitoring their HDIT patients (see ch. 7).
- Physicians could be involved in the development and periodic review of providers' intro-d quality assurance programs. This activity might increase physicians' sense of control over the quality of home services they prescribe for their patients.

Service Coordination

The decentralized nature of HDIT services poses an additional challenge for quality assurance. OTA's discussions with HDIT providers and patients strongly suggest that communication between the patient, referring physician, all HDIT staff, and any other parties either directly or indirectly involved in the patient's care are key to goodquality care and favorable outcome of therapy. Communication and coordination may be of particular concern to providers who subcontract pharmacy or nursing services.

Furthermore, some elderly patients require home care services beyond those generally required by younger, healthier patients on HDIT (e.g., home health aide services) (see ch. 3). Coordinating HDIT with general home health services (e.g., making sure home health aide staff are aware of the patient's HDIT regimen) can improve quality of care, reduce confusion for the patient, and cut overall costs of care by eliminating unnecessary duplication of services.

Many existing specialized HDIT providers have limited experience with elderly patients who require additional home services (see ch. 4). Of the various types of HDIT providers, Medicare-certified HHAs are probably the most likely to have had experience in coordinating these services because they provide the full range of Medicare-covered home care. Under anew Medicare benefit, Federal policy could address these issues by establishing explicit requirements for coordination of services between all agencies or individuals involved in patient care.

Existing Standards for HDIT Providers

Standards Issued by National Organizations

Standards developed by national organizations often serve as models for Medicare provider requirements. Existing published standards for HDIT providers or services, which vary in scope and detail, address areas such as:

- protocols and procedures for patient assessment and care,
- equipment and facility standards,
- staffing requirements and qualifications,
- the physician's role, and
- internal quality assurance program requirements.

Some of these standards are issued as guidelines for voluntary accreditation; others, for purposes of general reference and guidance. The two organizations currently offering accreditation for HDIT providers are JCAHO and NLN/CHAP (237). Other organizations that have issued advisory or model standards applicable to HDIT include the National Alliance for Infusion Therapy (NAIT)[5] (230), the Intravenous Nurses Society (INS) (174), and the National Association of Boards of Pharmacy (231). Most of these standards have been developed during the past few years and have undergone frequent revisions.

Although an increasing number of HDIT providers are obtaining accreditation, others have not pursued it. As of September 1991, JCAHO had accredited approximately 920 home infusion providers, including freestanding infusion companies, hospital-based providers, and visiting nurses associations that provide HDIT under contract (33). NLN/CHAP, which began offering accreditation for

5 Formerly the Alliance for Medical Nutrition.

HDIT in late 1989, had accredited a total of 38 providers as of November 1991 (95).

It is impossible to determine the actual proportion of existing home infusion providers that are accredited because of differences in the way providers are counted. Depending on the organization of a multisite provider and the way in which it seeks accreditation, JCAHO and NLN may accredit the parent organization as a whole or each individual branch or franchise separately (95). Furthermore, because both NLN and JCAHO have a 3-year accreditation cycle, some providers accredited only for noninfusion-related home health care may have begun to offer infusion therapy services in the interim. These providers, although accredited, are not accredited specifically for HDIT.

Standards Issued by Health Insurers

Some private third-party payers that cover HDIT services have developed specific standards or guidelines for providers that wish to obtain reimbursement. The purpose of these guidelines is both to assure quality and to contain costs.

Blue Cross and Blue Shield of the National Capital Area (BCBS/NCA), for example, has issued participation guidelines for home health care providers that specifically address HDIT services delivery (see box 5-A). Although the BCBS/NCA guidelines do not specify core staffing requirements, they do require that a single provider assume responsibility for the provision of all services. They also require that the primary provider hire, on at least a consulting basis, a licensed pharmacist proficient in infusion therapy practice. Under the guidelines, HDIT providers must have written policies and procedures regarding frequency of physician and staff contact, patient selection criteria, and monitoring requirements for each type of therapy they provide. Providers who deliver infusion antineoplastic therapy and total parenteral nutrition services must meet some additional requirements (42).

While many standard-both national standards and those issued by health insurers-require providers to implement an ongoing internal quality assurance program (178,230,237), few offer specific guidelines for structuring such a program. BCBS/NCA is an exception (see box 5-A) (42).

Developing Quality Indicators for HDIT Providers

Most HDIT providers operating today have some form of internal quality assurance program, although the degree of effort varies considerably (364). Most providers focus on structural and process measures of quality (see box 5-B). These include such measures as reading and recording of patient vital signs during each nursing visit, completion of required continuing education by provider staff, and documentation of patient training activities.

Although structure and process measures can provide a strong quality assurance framework for the operations of an HDIT provider, specific quality of care problems may go unnoticed if patient outcome criteria are not also examined regularly (96). Potential criteria that can be examined in an ongoing internal quality assurance program are as numerous as the provider's list of written protocols for patient care. If performance of every protocol is documented in the patient records, then those records can be examined for compliance in every aspect of patient care. Depending on the number of patients served by a provider, review can be performed on all or on a sample of patient records. Specific outcome criteria that might be helpful to monitor include:

- rate of equipment malfunction (103);
- rate of nonroutine infusion restarts and reasons for these restarts (81);
- level of patient satisfaction with HDIT services and specific reasons for dissatisfaction (this could be accomplished through periodic retrospective patient satisfaction questionnaires) (219);
- specific patient complaints (e.g., request for a different professional caregiver) (219);
- rate of infusion therapy-related complications (e.g., phlebitis, infection, catheter occlusion, air embolism, infiltration) (96);
- rate of early detection and treatment of drug side effects (e.g., laboratory testing performed and results reported according to protocols, appropriate followup by physicians and nurses) (96); and
- effectiveness of HDIT (therapeutic goals achieved; no recurrence of condition noted 6 months after last treatment) (96).

Studying outcomes of HDIT is useful not only for the identification of noncompliance with specific

Box 5-A—Blue Cross and Blue Shield of the National Capital Area Standards for Participating Home Care Providers

Blue Cross and Blue Shield of the National Capital Area has published standards for home infusion providers who wish to obtain reimbursement from the plan. These standards address areas such as:

. licensure, organization, governance, and management;
development of written policies and procedures for all treatment modalities;
• monitoring frequency of physician contact;
. professional training and continuing education for nurses and pharmacists;
coordination of services;
• 24-hour availability of services;
. testing and maintenance of equipment;
* patient assessment and training;
• arrangements for collection, analysis, and reporting of laboratory test results; and
. availability of social work services to patients as needed.

In addition, the standards set the following specifications for an ongoing internal quality assurance program:

1. There is evidence of an ongoing quality assurance program supported by the provider to monitor the quality and appropriateness of patient care and services provided. The program includes, but is not limited to:
   assessment of the competency of personnel providing services, including the appropriateness of responsibilities assigned to each individual;
   . appropriate execution of physician orders;
   * effective emergency response to patient or caregiver problems;
   • evaluation of services including review of provider policies and procedures;
   * ongoing, concurrent review of any infections, complications, adverse reactions, and therapeutic failures;
   * review of the records of maintenance, repairs, and faulty supplies for all equipment;
   * evaluation of the effectiveness of the patient and caregiver training and education program; and
   • hiring a fully licensed pharmacist as a consultant to the staff of the infusion therapy program to participate in the development of educational programs, policies and procedures, and ongoing quality assurance activities.
2. Assessment of documentation within the medical record includes, but is not limited to:
   designation of the attending physician primarily responsible for the patient's therapy at home;
   * initial and ongoing physical and psychosocial assessments;
   • evidence that the patient and/or caregiver has completed training;
   presence of a plan of treatment;
   signed and dated progress notes for each home visit and telephone contact noting: treatment administration, response to therapy, complications or adverse reactions, modification in prescription, patient/caregiver compliance, condition of infusion site, and catheter site changes.
   appropriate and complete diagnostic and therapeutic orders signed by the attending physician;
   • relevant laboratory test determinations and procedure findings;
   * pharmacy dispensing record including date and time; solution type, volume, and lot number, medication additives; and dose and infusion rate;
   documentation of ongoing contact with the attending physician and other agencies/vendors providing patient services;
   • supplies and equipment used; and
   a summary statement at termination of therapy which includes results of therapy, complications, outcomes, and disposition or status of the patient upon discharge from care.

SOURCE: Blue Cross and Blue Shield of the National Capital Area, ' 'Guidelines for Participation of Home Care Providers," Washington, DC, February 1989.

protocols, but also for gaining a general base of knowledge about the problems associated with HDIT and how to resolve them. As HDIT evolves, careful documentation of patient problems and outcomes will be crucial to the development of rational coverage and delivery policies. Some providers have already begun to incorporate specific outcome measures into their quality assurance programs. NLN/CHAP accreditation surveys for home infusion providers also incorporate outcome

Box 5-B-Quality Assurance in Home Care

Quality assessment is the measurement and evaluation of the quality of health care provided to individuals or to groups of patients. ***Quality assurance*** is the conduct of activities that safeguard or improve the quality of health care by correcting deficiencies found through quality assessment (363).

Quality assessment involves the application of structural, process, and outcome measures (98). Structural measures assess whether the availability and organization of resources (e.g., quality of personnel, equipment, facilities, and coordination of services) are adequate to assure a certain standard of quality. Process measures examine the amount of careprovided and the performance of health professionals who deliver it by comparing actual care delivered with accepted standards. Outcome measures assess the relative effectiveness of structure and process in determining quality of care by looking at specific patient outcomes (e.g., health status, incidence of complications, satisfaction with care). While structural and process standards can measure the ***capacity*** to deliver quality care, only outcome measures can determine whether providers are in fact meeting that capacity (292,293).

Quality assessment and assurance methods for ambulatory and home care are less developed than those for inpatient care (48,192,252,253,292,395). Quality assurance efforts in home care to date have focused on structural and process measures rather than patient outcomes, which are less well-researched and designed. State licensure, accreditation, and Medicare certification are the three primary quality assurance mechanisms used in home health care today (292).

However, sophisticated and more narrowly defined home services such as infusion therapy may be conducive to outcomes assessment in a way that other home health services are not. For example, IV antibiotic therapy outcome can be measured by resolution of the infection within a given time period and by nonrecurrence of that infection for a specific time period following completion of therapy. In contrast, "outcomes" of ongoing home health services for a chronic arthritis patient are less tangible.

Even the most sophisticated and comprehensive quality assurance program cannot guarantee successful patient outcomes, because factors other than quality of care can affect these outcomes (25,47,293). This maybe particularly true in the home setting where many of the factors that can affect patient outcomes are beyond the provider' control (25). Thus, screening patients for some of these potentially problematic factors (e.g., ability to perform self-care tasks adequately) becomes key in HDIT quality assurance.

and consumer-oriented measures of quality (237), and JCAHO has put together a task force to examine outcome-oriented quality indicators for HDIT (229).

State Regulation

Medicare sometimes looks to State regulatory mechanisms as one means of assuring the level and quality of services offered by participating providers. Generally, if a State has applicable licensure or certification laws, Medicare requires that a provider—whether it be a physician, a hospital, or an HHA-be licensed or certified according to those laws in order to qualify for reimbursement from the program (74).[6]

The extent to which State licensure and certification laws can serve as reliable and consistent measures of quality for nonhospital health care settings, however, is limited (352). The requirements set forth by States vary considerably in depth and scope, and some States have no regulations at all for certain types of providers (e.g., HHAs and hospices) (352). As of March 1991, for example, 11 States still had no licensure requirements for Medicare-certified HHAs, and 20 States had no licensure requirements for non-Medicare-certified HHAs (233).[7]

To the extent that HHAs are involved in any aspect of HDIT, Medicare regulation and existing State regulation of HHAs could serve as an indirect means of assuring the quality of those HDIT services. At present, however, Federal regulation of Medicare-certified HHAs does not directly address quality assurance issues unique to HDIT or other high-technology home services (352). The extent to

[6] *The same rule was* to apply under the proposed regulations for home IV drug therapy providers issued pursuant to the MCCA (54 F.R. 172—see appendix C).

[7] Medicare began covering services provided by HHAs that met its conditions of participation in 1966. Initially, private HHAs were allowed to participate in the Medicare program only if they were licensed pursuant to State law (74). In 1981, requirements were relaxed to allow for the participation of private agencies in States with no licensing mechanism (74).

which State HHA regulations specifically address HDIT services is unknown, but since many States have used Medicare COPS as a model for their own HHA regulations (232,233,292,352), it may be presumed that it is very limited. For new services such as HDIT, it may be years before States develop specific licensure or certification mechanisms, if they develop them at all.

Most of the existing State regulations for HDIT providers have been developed and implemented by State boards of pharmacy. A May 1989 survey of all 50 State boards of pharmacy found that 15 States had published some relevant regulations and an additional 18 States were planning to do so (210). The scope of these regulations varies considerably from State to State, however. Some apply only to preparation of parenteral drugs, while other States define and regulate a broader role for pharmacies in HDIT provision:

- At least two States require separate licensure for home infusion therapy pharmacy providers (366). Regulations in Washington State address the full scope of home infusion therapy services, including nursing, pharmacy, delivery, coordination, and physician involvement. Washington has even designed and implemented special training programs for inspectors of home infusion pharmacies/providers (210). Regulations in New Jersey are more limited in scope (295).
- An additional 20 States claim to have some form of home infusion therapy regulations in place, but OTA found that most of these regulations address only the preparation and labeling of parenteral solutions rather than the broader range of home infusion therapy services (366). Regulations typically address areas such as physical plant, staffing, procedures, internal quality assurance, and recordkeeping (63,366). Most States have specific regulations for the handling and preparation of cytotoxic drugs (e.g., antineoplalstic drugs) (63,366). Regulations vary, however, in their description of the scope of pharmacist responsibilities for patient care (63).
- As many as 28 States claim they do not currently regulate home infusion pharmacies. Of these, eight claim that such regulations are currently under development (210,366). However, some of these States may actually regulate parenteral drug preparation at a level commensurate with that of States that claimed they do regulate home infusion pharmacy (366).

The Federal Role in HDIT Quality Assurance

The high level of coordination and skill involved in the provision of HDIT services raises concerns that, under Medicare, all providers might not offer a consistent acceptable level of quality services. Under a separate HDIT benefit, Medicare could exercise control over the quality of HDIT services by:

1. establishing COPS for providers, implementing survey and certification procedures to ensure compliance with those COPS, and applying penalties for noncompliance;
2. conducting case-by-case review (both prior and retrospective), either through FIs or PROS;
3. developing a list of covered drugs that are generally safe and appropriate for home delivery; and
4. creating a system of payment that provides appropriate incentives for the referral of patients to HDIT and for the participation of qualified health professionals (nurses, pharmacists, and physicians) in the conduct of that care.

The following section focuses on the first two mechanisms. Coverage and payment considerations are discussed in chapters 6 and 7 of this report, respectively.

Current Medicare Quality Assurance Efforts Relevant to HDIT

Under Medicare, all qualifying providers[8] must comply with certain conditions set forth by the Secretary of the Department of Health and Human Services in order to obtain reimbursement for their services (42 CFR 417). These conditions are Medicare's most systematic method of assuring quality of care at the provider level.

Existing Medicare coverage for HDIT is limited and fragmented. The key sources of coverage are the

[8] "Providers" under Medicare are defined to include the following: hospitals, skilled nursing facilities, comprehensive Outpatient rehabilitation facilities, home health agencies, hospices, and providers of outpatient physical therapy or speech pathology services (42 CFR 417,416).

Part A home health care benefit and the Part B durable medical equipment (DME) benefit (see ch. 6). Existing COPS for HHAs are broad and do not address many of the quality assurance concerns specific to HDIT. DME suppliers, because they are suppliers of equipment rather than providers of services, are not subject to any direct Medicare quality control measures in spite of the fact that they are another major source of Medicare-covered HDIT.[9]

Under Part A, certified HHAs are required to comply with specific COPS that include staff qualifications and annual program evaluation by a group composed of HHA staff and consumers (42 CFR 484). These COPS, discussed in more detail later in this chapter, are for home health services generally and do not specifically address HDIT quality concerns. Medicare PRO oversight of home health services, also discussed later in the chapter, has been limited and indirect.

Drugs and other fluids administered via an infusion pump are occasionally covered under the Part B DME benefit along with the pump (see ch. 6) (365). Direct Medicare quality assurance efforts are virtually nonexistent, however, because DME suppliers who bill Medicare are not subject to any specific COPS or conditions of coverage (74). They are required by law to provide instruction in the operation of DME, but the degree to which they do so is currently not documented or regulated, and in some cases it may consist merely of including written manufacturers' instructions in an equipment delivery (156).

The Safe Medical Devices Act of 1990 requires that device user facilities[10] report medical device malfunction events that contributed to the death or serious illness or injury of a patient to either the manufacturer or the Secretary of the Department of Health and Human Services within 10 days of their occurrence (Public Law 101-629).[11] Such reports could be useful for identifying and monitoring the use of potentially harmful HDIT devices (e.g., an infusion pump prone to malfunction).

Because current Medicare coverage for the components of HDIT is very fragmented, a comprehensive HDIT quality assurance program is not possible at present. The responsibility for quality assurance is therefore implicitly relegated to the prescribing physician, who often has little control over the services provided to HDIT patients. Some carriers (the Part B FIs) have been reluctant to cover drugs under the DME benefit because they perceive the lack of a defined 'infusion provider' '—and the qualifications that such a designation might require-as a quality problem (365). Some carriers go so far as to require preauthorization of all claims involving payment for drugs under the DME benefit (365).

Proposed Requirements Under the MCCA

If a Medicare HDIT benefit were created, COPS would probably need to be established specifically for providers of this service. Fortunately, HCFA has already given considerable thought to developing COPS for HDIT providers, because the now-repealed MCCA was to have included home IV drug therapy .12 Proposed regulations issued pursuant to the MCCA specified detailed COPS for qualified providers (see app. C). The proposed COPS addressed:

- compliance with Federal, State, and local laws,
- governing body and administration,
- patient selection,
- plan of care and physician review,
- maintenance and handling of central clinical records,
- core staff and services,
- nursing services,
- pharmacy services,
- patient and family caregiver evaluation and instructions,
- written protocols and policies,
- provider quality assurance activities, and
- infection control (54 F.R. 172).

9 Medicare also covers total parenteral nutrition, another form of home infusion therapy, under the Part B prosthetic devices benefit (see ch. 6). Coverage is limited to nutrients, equipment, and supplies. Medicare has no structural quality assurance requirements for total parented nutrition (TPN) providers.

10 Device user facilities include hospitals, ambulatory surgical facilities, nursing homes, or outpatient treatment facilities that are not physicians offices (e.g., HHAs, DME suppliers) (Public Law 101-629).

11 Reporting provisions of the Safe Medical Devices Act of 1990 were effective as of Nov. 29, 1991.

12 To develop the COPs, HCFA sought guidance from industry representatives, health professionals, professional associations, organizations that currently accredit or publish standards for home IV drug therapy providers, and other knowledgeable parties (54 F.R. 172).

Although the proposed rules were never made final, they generated mostly positive comments from responding organizations (167). The remainder of this section focuses on specific areas of the proposed COPS that deserve additional attention if a new benefit were to be implemented.

Routes of Drug Administration

The MCCA benefit was to cover IV therapy alone. If Congress were to develop an HDIT benefit that also covered other routes of administration (e.g., subcutaneous, intraspinal), relevant COPS and other regulations would need to address the attendant differences in intensity of services, required equipment and supplies, and specific techniques used. For example, the proposed conditions issued pursuant to the MCCA required that peripheral catheters be changed at least every 3 days (54 F.R. 172). Although existing standards support the 3-day rotation of peripheral *venous* catheters, peripheral arterial catheters are generally changed less frequently, and subcutaneous infusion needles are changed every 48 hours (see ch. 3) (174).

Patient Care Policies and Physician Review

The proposed regulations specified that it would be the referring physician's responsibility to initially determine whether home IV therapy is appropriate for the patient and to prescribe the drug regimen for that patient. In addition, they required the referring physician to review the plan of care at least every 30 days (54 F.R. 172).

The proposed rules made no specific requirements for frequency of contact between patient and physician during the course of therapy, however. For a substantial proportion of HDIT patients, a 30-day minimum review requirement might mean that their plan of care would undergo only initial review, leaving the possibility that some complications or side effects of therapy would go unnoticed. More frequent physician contact during therapy may be especially appropriate for elderly patients with multiple health problems. Specific requirements for patient-physician or provider-physician contact could even be established by type of therapy or type of condition. For example, some programs recommend weekly physician visits for patients on antibiotic therapy (91). In addition, HCFA could require more frequent comprehensive review of the plan of care by the referring physician.

Patient Selection

The proposed rule required that a provider screen each patient before acceptance, and that this screening be performed by a multidisciplinary team of experts in home IV therapy. Both medical criteria (e.g., the patient's clinical status) and nonmedical criteria (e.g., patient's ability to undertake self-care) were to be considered in patient selection (54 F.R. 172).

The proposed conditions did not provide specific screening criteria to use in determiningg that patients "have a clinical status that allows IV drugs to be safely administered at home. " Although it is ultimately the physician's responsibility to determine whether a patient's medical condition is sufficiently stable for HDIT, additional requirements might aid providers or other parties involved in initial determination of appropriateness of HDIT (e.g., PROS or FIs). As discussed below, the MCCA mandated PROS to perform prior authorization on all home IV therapy claims. Presumably, each PRO would develop its own screening criteria to determine safety and appropriateness. Separate criteria in each PRO jurisdiction, however, could lead to inconsistency in coverage and quality of care.

In addition, if a new Medicare benefit were to cover HDIT for patients not capable of self-care, more explicit patient selection and provider services requirements would need to be developed.

Staffing and Services

The Health Care Financing Administration(HCFA) proposed that home IV therapy providers meet certain staffing and service requirements. Specifically, the proposed regulations stated that:

- Home IV providers must directly employ at least one full-time-equivalent (FTE) nurse or pharmacist.
- The home IV provider must perform the following services directly:
  - -developing, supervising, and coordinating all nursing and pharmacy services;
  - —assuring that only qualified personnel provide home IV services;
  - -consulting with pharmacists involved in patient care to coordinate the plan of care with the physician; and
  - —performing quality assessment activities including drug regimen review.

There was extensive debate both before and after publication of the proposed rule regarding core staffing requirements (167) (52 F.R. 172). The rationale behind the proposed requirement for either a full-time nurse or a full-time pharmacist was that HDIT involves both nursing and pharmacy services, and that a provider should therefore have at least one of either of these professionals within its direct employ. A nurse or a pharmacist alone, however, would not have been able to provide all of the proposed core services. For example, a nurse would not be capable of drug regimen review, and a pharmacist would not be capable of developing and supervising nursing services. HCFA had initially considered requiring that *both* a nurse and a pharmacist be employed directly, but professional provider organizations objected on the grounds that this would disenfranchise many existing providers (e.g., HHAs with no in-house pharmacy) (54 F.R. 172) (167).

A possible solution to this problem would be to require that providers who have only an RN under direct employ maintain a consulting contract with a pharmacist who is experienced in HDIT. This pharmacist would assist the HDIT provider on an ongoing basis with development, coordination, and evaluation of pharmacy services and with periodic drug regimen review. (This model is similar to that used by BCBS/NCA (42)).

Nursing Service-The proposed rule required that ***all nurses*** providing home IV services be RNs who had at least 2 years' experience in patient assessment and infusion therapy. Nurses were required to be proficient in all procedures directly related to IV therapy and the insertion of all types of needles and catheters commercially available (52 F.R. 172).

The comprehensiveness of these proposed skill requirements may be unrealistic in the existing specialized HDIT market. HDIT providers—especially those with numerous staff-tend to divide patient care responsibilities among nursing staff according to individual nurses' skill levels (see ch. 3, box 3-C). For example, one nurse may specialize in PICC line placement, performing it on all of the providers' patients, while another may be responsible for placement, maintenance, and repair of standard peripheral catheters. Still other nurses may specialize in the care of patients with central access devices.

In addition, although some HDIT-related procedures are skilled procedures that *mu@ be* performed by an RN (e.g., venipuncture), other tasks (e.g., dressing changes and central catheter care) may be performed by other staff who have been trained properly and who work under the supervision of an RN. Some providers use licensed practical nurses to perform noninvasive catheter care and drug administration procedures (3).[13] Greater flexibility in staff skill requirements could improve the ability of providers to recruit qualified staff. For example, most home infusion provider nursing staff today are not proficient in inserting PICC lines, a type of "commercially available" catheter (see ch. 3). Although the level of proficiency and experience described in the proposed conditions is not reasonable to require of each *individual* nurse involved in HDIT, it is reasonable to require it of at least one nurse who is employed directly by the provider.

Pharmacy Services-HCFA did not address the qualifications pharmacists, despite the fact that home infusion pharmacy requires expertise and knowledge as specific as that in infusion nursing. In the future, specific experience in relevant aspects of HDIT phamacy (e.g., drug compounding, patient education, drug therapy monitoring, drug regimen review) could be required of pharmacists whose responsibilities included such activities.

HCFA's proposed standards for drug preparation were also inconsistent in some areas with existing private standards for home infusion pharmacies. For example, the proposed regulations would have allowed either clean work benches *or* laminar flow hoods for the preparation of IV drugs (54 F.R. 172). In contrast, JCAHO, NLN/CHAP, NAIT, and American Society of Hospital Pharmacists (ASHP) standards all require the use of laminar flow hoods to protect against microbial and particulate contamination (178,199,230,237).

Patient and Family Caregiver Assessment and Training

Proposed COPs required that an RN perform patient and family caregiver evaluation and educa-

13 HCFA's experience that "none of the entities [it] contacted allowed anyone but a registered nurse to furnish nursing services connected with IV drug therapy" (54 F.R. 172) may have been influenced by the fact that, at the time the proposed rule was published, it had contacted mostly proprietary home IV drug therapy providers (167).

tion. This requirement would have been problematic, for two reasons. First, patient and family caregiver evaluation is often a multidisciplinary effort that involves not only the nurse but the referring physician, pharmacist, and other health professionals such as a nutritionist or social worker. Second, some aspects of patient/family caregiver instruction (e.g., discussion of side effects of therapy, use of infusion devices, self-care techniques) may sometimes be appropriately given by pharmacists or other types of health personnel, such as specially trained pharmacy technicians (see box 3-C) (15). Future COPS for HDIT providers could reflect this practice by allowing a broader range of health professionals to perform some of these functions, perhaps under the supervision and coordination of a qualified RN. Also, any future COPs might want to specifically address patient responsibilities in HDIT.[14]

Protocols and Policies

First-Dose of Medication—Proposed COPS required that the first dose of any IV therapy be given under the direct supervision of a physician *or* nurse who is equipped with resuscitation medication and equipment to treat anaphylaxis (54 F.R. 172). Alternatively, under a new benefit, HCFA might require that the first dose of infused drugs with a known potential for allergic reaction or other complications always be delivered under a physician's supervision.

The nature of the supervision could vary depending on the setting in which the initial dose is given. For example, patients who are discharged to HDIT from the hospital could be required to receive their first dose in the hospital where physicians are readily available. For outpatient-initiated therapy, patients could be required to receive the first dose in a physician's office or hospital outpatient setting. For outpatients who are homebound, special exceptions could be made or, alternatively, a physician home visit could be required for the initial dose.

Catheter Care-Catheter care requirements in the proposed rule were generally consistent with recognized standards of infusion nursing practice (174,199,237). In light of the rapid pace of technological innovation and change in HDIT, however, rigid standards such as those proposed might have required frequent updating to stay abreast of current practice. For example:

- **The** proposed rule required that the sites of all peripheral catheters be rotated by a nurse at least every 3 days (54 F.R. 172). Some newer catheters can remain in place longer than 3 days (see ch. 3) (364). Alternatively, HCFA could require that the catheter site be inspected by a nurse at least every 3 days and changed as necessary.
- The proposed rule required that IV administration sets be changed at least every 24 hours (54 F.R. 172). Although support for this requirement may be found in existing standards or professional literature, the appropriate frequency of administration set change varies with the particular therapy and dosing fiquency. For example, patients on continuous infusion may only change their administration set every 5 to 7 days, while patients using disposable infusion devices may change their administration sets up to 4 times a day by default, because the administration set is integral to the device. A less rigid requirement for administration set change could thus be appropriate.

Air-Elimination Filter and Catheter Testing—As an additional measure of quality control, HCFA proposed that nurses routinely collect a random sample of discarded catheters and air-elimination falters and send them to a laboratory for analysis of particulate and microbial contamination (54 F.R. 172). Both ASHP and the Association for Practitioners in Infection Control objected to this condition on the grounds that the catheters and falters could easily become contaminated between the time they were removed from the patient and the time they were examined in the laboratory (1,199). Both these groups recommended culturing the catheter or filter only when there were clinical signs of possible infection (1,199).

Drug Therapy Review—The proposed rule required that the pharmacist review the prescribed combination of IV drugs and equipment for appropriateness before therapy began. In addition, the pharmacist was to be required to review the appropriateness of drug therapy at least every 3 days and

14 For example, the patient/family caregiver might be instructed and required to document on a chart each drug and solution administration or other HDIT-related procedure (e.g., catheter flushing, administration set change, dressing change) and note any attendant difficulties they experienced. These charts could be incorporated into the central clinical record to complement nurse and physician notes.

report significant findings to the physician (54 F.R. 172).

Review every 3 days may not be necessary in all cases, and it may sometimes be logistically difficult if the pharmacist must meet with the patient's nurse in order to review appropriateness. Some providers have most staff on site and can hold regular meetings (e.g., routine drug regimen review once a week) attended by all members of the provider staff. Providers who send staff to patients' homes and/or subcontract for pharmacy services, however, may have to resort to other modes of communication (e.g., telephone, facsimile, extensive patient encounter notes) to accomplish the conferencing necessary for ongoing drug regimen review. HCFA might instead require pharmacists to review appropriateness of therapy at least once a week and whenever requested to do so by patient care staff.

Patient Rights and Responsibilities-The proposed conditions specified that treatment should begin only if the provider is capable of furnishing care at the level of intensity required by the patient. In addition, providers were to inform patients of their responsibilities and rights in writing upon initiation of therapy. The proposed rule also required providers to establish procedures for patient complaints (54 F.R. 172).

Under anew benefit, HCFA might want to further require that written consent be obtained from patients before therapy begins. For instance, providers could be required to obtain signed statements from patients documenting that they fully understand and are able and willing to perform all aspects of required self-care, that they are aware of the risks associated with their therapy, and that they understand what their share of costs for the services are expected to be.

Provider Quality Assurance Activities

The proposed conditions required home IV providers to maintain ongoing, systematic quality assurance programs to evaluate the quality and appropriateness of patient care, correct deficiencies, and improve patient care (54 F.R. 172). A written evaluation plan was to include scope and objectives of quality assurance activities, specific activities to be monitored, methods for evaluation and reporting of results, mechanisms for corrective action, and staff responsibilities for each activity. Home IV providers were to be required to collect and analyze data *at least annuully* on the length of therapy by diagnosis and treatment; patient complications and rehospitalizations; and the nutritional status of patients. In addition, providers would have been required to determine that activities had been carried out appropriately (e.g., that delivery of drugs and equipment was timely, that any peripheral catheter patient had their catheter rotated by a nurse every 3 days, etc.) (54 F.R. 172).

The proposed quality assurance standards lacked specificity in some areas. For example, they failed to specify whether the quality assurance activities (e.g., collecting data on negative outcomes) should be applied to all cases or to a sample of cases. Also, although the proposed COPS required the provider to specify "staff responsibilities for each activity in the quality assurance program," they did not specify where activities should involve both nursing and pharmacy Staff.

Nor did the rule specify a role for the patient in the ongoing quality assurance program. Providers could have been required to conduct an exit interview with a sample of patients (or with all patients), for example, to verify that care documented in the clinical record was in fact performed.

Determining Provider Compliance With Conditions of Participation

Activities of State Survey Contractors

To determine compliance with its COPS, HCFA generally relies on a State agency (usually a department of health or department of aging) with whom it contracts to conduct periodic surveys of all facilities in the State (351). State surveyors are given guidelines and, in some cases, specific assessment tools, to use in the survey process for each type of facility.

Because the proposed COPS for home IV therapy providers were never implemented, mechanisms for determining provider compliance were never tested. However, past experiences with HHAs can shed light on potential problems in determiningg compliance with any future Medicare COPS for HDIT providers.

In order to qualify for reimbursement through the Medicare program, HHAs must comply with COPS that address the following two general areas:

- *administration* (acceptance of patients, plan of care, patient rights, medical supervision, disclosure of information, organization and administration of services, policy review), and
- *furnishing of services (staff* qualifications and *tr*aining, maintenance of clinical records, program evaluation, survey and certification process) (42 CFR 484).

Compliance for both initial and continuing certification is determined by surveyors[15] from a State agency who make an unannounced visit to the HHA at least once every 15 months. On each visit, a "standard survey' is conducted that assesses compliance with a specified subset of the COPS. The survey visit can include review of a random sample of medical records,[16] review of written patient care protocols, verification of staff qualifications and training, site visits to patients' homes t. witness the direct provision of care and interview patients regarding their satisfaction with the HHA services. Based on the standard survey, the surveyor makes a judgment as to whether the HHA seems to be providing standard or substandard care. If it is judged substandard, the State conducts an extended survey that assesses compliance with the exhaustive list of COPS. If the HHA fails the extended survey, sanctions can be applied.

The Omnibus Budget Reconciliation Act of 1987 (OBRA-87)[17] mandated that quality of care measures based on patient outcomes be incorporated into the HHA survey procedure. Measures such as death or readmission to a hospital or nursing home during or shortly after termination of treatment are among those to be used to detect problems (42 CFR 484). OBRA-87 also mandated that visits to the homes of HHA patients be included in the survey process to enable direct observation of care currently being provided, and to ensure that procedures documented in the patient record were actually performed (351). Accordingly, HCFA has published revised COPS for HHAs (42 CFR 484) and has issued instructions to State survey agencies on how to conduct outcomes-oriented surveys (370).

Because the outcomes-oriented survey and certification mandates did not go into effect until March 1991 (132), it is too early to know whether they are in fact improving the quality of HHA care. However, a 1989 study by the U.S. General Accounting Oftlce (GAO) found numerous problems with the conduct of HHA surveys by State agencies prior to implementation of the new provisions. These included:

- inadequate guidance and oversight by HCFA on conduct of surveys;
- inconsistent interpretation by State surveyors of requirements for compliance with Medicare COPS;
- inconsistency in scope of surveys and methods used to select samples of records for review;
- lack of coordination between State survey agencies, FIs, and Medicare PROs;[18] and
- lack of personnel training standards for high-technology services such as infusion therapy (351).

Although some of these problems have been addressed in the new instructions issued by HCFA (132), it remains to be seen whether they will be resolved.

If future HDIT coverage under Medicare entails a new class of certified providers, similar problems could arise. Problems might be avoided by improving the clarity of the conditions themselves, offering more thorough and consistent guidance to the State agencies that conduct the surveys, and mandating and facilitating cooperation between all organizations involved in HDIT quality of care review (e.g., PROS, FIs, and relevant State licensing agencies) (351).

Reliance on Standards Issued by National Accrediting Bodies

Section 1865 [a] of the Social Security Act permits HCFA to grant "deemed status' '-i.e., to consider certain health facilities as meeting any or all of Medicare's COPS for that type of facility-to facilities accredited by a national accreditation program (SSA, sees. 1864, 1865[a]). Deeming authority is monitored through a validation review process in which a small sample (5 percent) of providers are surveyed directly by HCFA to test how

15 HHA surveyors are always registered nurses.

16 Sample size depends on the size of the agency and is defined as a fixed number of records rather than a percentage (132).

17 Public Law 100-203.

18 PROs are required by law to coordinate their efforts with other reviewing bodies.

well the accrediting organization's standards continue to reflect Medicare's COPS (55 F.R. 51434).

Until last year, HCFA had extended deemed status only to hospitals accredited by JCAHO (127).[19] In October 1991, HCFA granted deemed status to HHAs accredited by NLN/CHAP. JCAHO has also applied to HCFA for recognition as a deeming authority for HHAs, but authority has not yet been granted.

It is unlikely that Medicare could initially rely on "deeming authority" as a mechanism for certification of HDIT providers due to inherent limitations of the standards themselves and the accreditation processes. First, accreditation surveys performed by national organizations may not be as good a measure of compliance with COPS as surveys by State agencies, because they tend to be conducted less frequently and are generally scheduled in advance, giving providers the forewarning they need to get "Up to speed." To date, JCAHO has conducted full surveys once every 3 years and has given providers a minimum of 4 weeks' formal notice (179).[20] NLN/CHAP also operates on a 3-year accreditation cycle, but it conducts abbreviated annual surveys in interim years and all of its site visits are unannounced (237).

Also, the cost of obtaining accreditation through JCAHO or NLN/CHAP may deter some smaller providers from seeking it. JCAHO's average fee for a single-site HDIT provider is approximately $4,800 for the full three-year accreditation period (33). The 1992 NLN/CHAP fee for a medium-sized single-site provider whose net revenue was under $1 million would be roughly $13,000 over a 3-year period (95).[21]

Case Review; Role Of Medicare Peer Review Organizations and Fiscal Intermediaries

While Medicare relies on State and national survey and certification processes to determine compliance with specific COPs, it generally relies on PROS to assess the quality and appropriateness of care at the individual case level. Mandated under the Tax Equity and Fiscal Responsibility Act of 1982 (Public Law 97-248), PROS have the authority to deny Medicare payment for inappropriate or unnecessary services and to discipline and/or sanction providers and practitioners to correct any unacceptable medical practices (363).

Because HDIT is a complicated service to deliver, and an HDIT benefit might be prone to overutilization if Medicare did not cover other outpatient prescription drugs (see ch. 6), some level of PRO review of claims would be warranted. A minimal level of PRO review would be retrospective review of a random sample of claims within each PRO jurisdiction. (Even this form of review is currently not required for Medicare home health services claims.) The most rigorous level of review, which was to be required under the MCCA benefit until 1993, would be prior review and authorization of all HDIT claims.

Current PRO Activities

To date, PROS have been involved primarily in review of claims for hospital and physician services. Due to the large volume of Medicare claims, review is usually conducted retrospectively on a random sample of claims. However, prior review is currently required for a few select procedures. (See box 5-C for a description of PRO prior and retrospective review processes.) PROS also review cases where quality of care has been brought into question, but this mechanism is limited by the ability and willingness of beneficiaries, providers, and health professionals to recognize and report suspected deficiencies or problems.

Because the initial PRO claims review is usually performed by individuals (usually nurses) who are not experts in the particular type of care provided, a key element to the prior review process is explicit review criteria for the service in question (183). At present, Medicare instructs each PRO to develop its own criteria for care, diagnosis, and treatment based

19 Until 1984, allowance for "deemed status" was limited to hospitals, skilled nursing facilities, and HHAs. Legislation in 1984 (Public Law 98-369) expanded the allowance to include rural health clinics; psychiatric hospitals; ambulatory surgical centers; clinical laboratories; hospices; comprehensive outpatient rehabilitation facilities; and clinic, rehabilitation agency, or public health agency providers of occupational therapy, speech pathology, or physical therapy services. This expanded authority has not been used, in part due to lack of relevant national accrediting bodies (127).

20 JCAHO has agreed to perform annual unannounced surveys as required under OBRA-87 if granted deeming authority by HCFA for HHA certification (287).

21 NLN/CHAP fee quoted includes annual fees (based on net revenue according to a sliding fee scale), cost of the initial visit (2 staff On-Site fOr 3 days), plus the cost of two additional survey visits (approximately half the cost of the initial visit) (95).

Box 5-C-The Medicare Peer Review Organization (PRO) Review Process

Prior Review

The physician or provider contacts the appropriate PRO for preauthorization, furnishing the plan of care and any additional documentation required for the review process (183). The first level of review, generally conducted by nurses, involves the application of explicit review criteria that have been developed by the PRO for the particular procedure or service. If the request for authorization fails to meet the initial explicit review criteria, it is referred to a physician reviewer who subjects it to implicit criteria based on his or her own clinical judgment and on professionally recognized standards of care. During this second level of review, the physician reviewer may request additional information from the referring physician. If the request fails second level review (after affording the physician and/or provider an opportunity to discuss the case), authorization is denied (183).

Retrospective Review

Each record identified for retrospective review undergoes five different basic reviews: generic quality screen, admission, discharge, invasive procedure and items/services coverage, and DRG (diagnosis-related group) validation. First-1evel reviewers (usually nurses) use explicit criteria to determine potential quality-related or utilization problems, If initial review uncovers a potential problem the records are referred to a PRO physician adviser for further review (105). Potential quality problems not detected by one of the five reviews (e.g., mismanagement of the case) maybe discovered by the initial nurse reviewer based on his or her medical judgement. In this case, the medical record would also be refereed to a physician adviser. If the initial reviewer can determine that a case failing one of the generic quality screens is not actually a quality problem, the case is not referred to a physician adviser (357).

A physician reviewer conducts a more in-depth examination of the medical record, based on his or her clinical judgment, to determine whether there actually is a problem. The review process also allows the attending physician and hospital an opportunity to discuss the specifics of the case in question. These discussions often reveal unique characteristics of the case that explain why it may have failed the initial screens. Most cases of potential problems are resolved this way (92).

If the physician reviewer determines after the discussions that the care provided was not medically necessary or that it should have been provided in another setting, a payment denial notice is sent by the PRC) tn the beneficiary, physician, provider, and fiscal intermediary. If the physician reviewer identifies a quality of care problem that is not cleared up after discussing the case with the patient's physician, the PRO will initiate appropriate interventions. These interventions may include physician education through a continuing medical education program, a corrective action plan, intensified review of the physician and hospital, or the initiation of a sanction review (357).

on typical patterns of practice within its geographic area or, where appropriate, on national criteria (374).

The retrospective review process uses separate quality screens that focus on potential problem areas and the overall appropriateness of care provided. The quality screens used to review the intervening HHA care received by readmitted hospital patients, for example, address such issues as the adequacy of patient screening and education, the provider's response to any changes in the patient's health condition, whether any deaths occurred within 48 hours of transfer to the hospital, and documentation of the plan for appropriate followup care (375).

Based on the information collected in medical record reviews, PROS produce physician and hospital "profiles" containing information on claims denials, mortality, and confirmed quality problems. The profiles are used to identify patterns of care that deviate from the norm for particular types of providers or deviate from established criteria and standards (350). The identification of an aberrant pattern of care may trigger a PRO's evaluation of a larger sampling of records from the physician or hospital in question. If PROS were to be involved in reviewing HDIT claims, the development and use of such profiles for HDIT providers might be an additional mechanism for safeguarding the quality and appropriateness of HDIT services.

At present, PROS' only involvement in quality assurance for home health is through hospital readmission review and beneficiary complaints (Public Law 99-509).[22] The PRO takes a 25 percent

[22] They do not review intervening care rendered in a physician office setting, emergency room, or any other setting, although emergency mom settings are proposed to be included as an intervening care review setting in the fourth contract cycle for PROS (53).

sample of all hospital readmission for a given year. From that sample, it reviews 20 percent of those readmission that received intervening care in a hospital outpatient clinic, HHA, or skilled nursing facility, obtaining relevant clinical records from the intervening care setting to determine whether the care provided was adequate and appropriate (53). The sampling method and small sampling size, however, limit the usefulness of these data in assessing quality at the individual provider level. Even the Keystone PRO in Pennsylvania, which was the first to review intervening care claims and has had the most experience with the process, had reviewed an average of only one patient per HHA per year in the State as of 1990 (53).

PROS also review HHA claims involving beneficiary complaints, but the flow of complaints to date has been highly inconsistent among States (53). This may be due to lack of beneficiary awareness of the availability of the PRO to investigate such complaints (44). Confidentiality provisions that prevent the PRO from informing the beneficiary of the results of such an investigation may also serve as a disincentive for beneficiaries to lodge formal complaints (53).

Proposed PRO Activities Under the MCCA Benefit

The MCCA called for extensive PRO involvement in oversight of home IV drug therapy services to ensure that care was being provided safely to an appropriate set of patients. Regulations and instructions issued pursuant to the MCCA articulated six areas of direct PRO involvement (54 F.R. 173).

Prior authorization:

1. Prior review of 100 percent of home IV therapy claims until 1993.[23] PROS were to complete review prior to initiation of services for inpatient starts, and within 1 working day of service initiation for outpatient starts.
2. Review of all requests for continuation of home IV therapy beyond the date or number of days specifed in the original request. These reviews were to be completed within 3 working days of the original termination date.
3. Review of all requests for changes of home IV drug therapy during the specified course of treatment, to be completed within 1 working day of the prescribed therapy change.

Retrospective review:

4. Postpayment review of a random 5 percent sample of all paid home IV therapy claims to determine provider and physician compliance with professionally recognized standards of care.
5. Periodic validation reviews of a random sample of claims in which initial approval was granted after the PRO had reviewed medical information via telephone but had not reviewed actual medical records, to validate the accuracy of information given verbally.
6. Prepayment review of any cases where PRO initial authorization was required but had not been completed.

Universal prior authorization for HDIT may not be necessary. The rationale for this requirement under the MCCA was to ensure safety and appropriateness of a relatively new and complicated mode of service delivery through a front-end mechanism. However, as the range of therapies that can be safely and effectively provided in the home setting expands and the volume of claims increases, it may no longer be practical for PROS to perform prior authorization on all claims. Furthermore, some therapies (e.g., certain antibiotic therapies) pose relatively little serious risk to patients. Claims for these might be handled through retrospective review unless HCFA felt there were a potential for mis- or overutilization of home IV antibiotic therapy (e.g., if oral drugs were usually sufficient for the condition but were not covered by Medicare).

Requiring PROS to perform prior authorization for all drug changes during the course of HDIT. services also may be unnecessary. As one alternative, Medicare could implement more limited safeguards, such as requiring additional patient instruction as to potential complications and mandating professional supervision during administration of the first dose of a new drug. Targeted retrospective review of drug changes by either a PRO or an FI could identify problems with particular drugs (or particular providers).

In some circumstances, there may be a need for ongoing review of a patient's HDIT to ensure that the course of treatment continues to be safe and effective for that patient. In the event of future Medicare coverage for HDIT, an appropriate regula-

~ PRO prior review of all home IV claims was mandated under the MCCA until 1993 and left at HCFA's discretion thereafter (44).

Box S-D—Proposed Scope of PRO Review for Home IV Drug Therapy Services Under the Medicare Catastrophic Coverage Act of 1988

From the time it received a request for review of home IV drug therapy services from either a physician or a health care facility, a PRO was to have 8 working hours to determine whether the services were reasonable, appropriate, and necessary for treatment of the patient's condition. Before approving home IV drug therapy service, the PRO was to have determined or to have been assured that:

* the patient's condition was such that inpatient hospitalization was not justified either:
  1) as a continuation of an existing hospitalization, or
  2) as a medically necessary and appropriate admission;
- the patient met the selection criteria specified in the regulations (see **appendix** C);
- the patient and/or caregiver had been or would be sufficiently trained to administer the drugs safely and effectively in the home;
- the patient or caregiver would independently administer at least one dose of the drug under supervision;
* the plan of care developed by the referring physician had enough information to support coverage of home IV drug therapy services;
- the covered drug was being used for one of the indications approved by the Secretary of the U.S. Department of Health and Human Services;
- the drug was medically indicated for treatment of the patient's condition;
- the prescribed dosage of the drug was correct for the patient's height, body weight, and other considerations;
- appropriate periodic monitoring had been or would be performed;
- the drug was not contraindicated;
- the home IV drug therapy services prescribed met professionally recognized standards of care; and
- the intavenous route of administration was the only safe and effective route for the patient.

SOURCES: 1%0 *Review* of Home IV Drug Therapy Services, guidelines issued to PROS by the Health Standards and Quality Bureau, Health Care Financing Administration, September 1989; 54 F.R. 173, Sept. 8, 1989.

tory body might want to identify specific drugs or conditions that warrant a more intense level of ongoing review and require that PROS or FIs perform such reviews.

Finallly, prior authorization of HDIT cases requires the ability for rapid response, since lack of responsiveness can delay hospital discharge or the initiation of therapy. Prior authorization of all HDIT claims within 1 working day might present serious administrative challenges to PROS. FIs might be an alternative body that could evaluate the appropriateness of HDIT on a prior, case-by-case basis. FIs have some experience with current HDIT coverage under the Part B DME benefit and the Part A home health benefit (365) (see ch. 6). Prior review might even be divided between PROS and FIs depending on type of therapy and the potential for its overuse. For example, prior review for therapies with which FIs have limited experience might be placed initially within the domain of PROS until a sufficient base of experience has been obtained to develop explicit review criteria. At that point, responsibility could be transferred to the FI, who could either continue prior review or resort to retrospective review. Alternatively, prior review could be made the responsibility of FIs from the start, with PROS reviewing only a random sample of claims retrospectively. FIs might also be a more appropriate choice than PROS for conducting change-of-therapy review in cases where HCFA deems this necessary.

Before the MCCA was repealed, HCFA had proposed generic quality screens to be used by PROS in prior review of home IV therapy claims (see box 5-D), as well as retrospective quality of care screens (53,167,376). HCFA had also developed diagnostic testing and other special criteria specific to the type of therapy and diagnosis to be used by PROS for review purposes (376).

If Congress were to create a new HDIT benefit, the work begun by HCFA in developing guidelines and screening criteria for prior and retrospective review of home IV therapy could serve as a starting point for the development of final screening criteria. New criteria would be needed, however, if the benefit were to cover alternative routes of parenteral administration, additional drugs, and/or beneficiaries who were not capable of self-care procedures.

Quality Assurance for Beneficiaries Who Receive Care Through Risk-Based Contracts

Under the proposed regulation, HCFA intended not to extend PRO review (either prior or retrospective) to home IV drug therapy services delivered to beneficiaries in risk-based health maintenance organizations (HMOs) or competitive medical plans (CMPs) (54 F.R. 173).[24] HCFA reasoned that:

[B]ecause risk-based HMOs/CMPs already have the clear incentive to prevent unnecessary utilization of covered health care services, it would be largely duplicative and, therefore, wasteful to have PROS use their limited resources to make the same determinations (54 F.R. 173).

Although PRO utilization review activities may have been duplicative of existing HMO/CMP initiatives, it is not clear that PRO quality review would have been duplicative. Because HMOs and CMPs are paid on a per capita basis for the services they render to Medicare beneficiaries, they have incentives to control the utilization of potentially costly services such as HDIT. They do not have as direct an incentive to control the quality of services delivered.

In 1985, Congress mandated PRO review of quality of inpatient and outpatient services provided to these beneficiaries after January 1987 (Public Law 99-272).[25] A recent study by GAO found serious deficiencies in PRO external review of quality of care provided in risk-based HMOs, citing data collection and sampling problems as the major barriers to adequate oversight (355). The GAO study also found that HCFA does not adequately assess the effectiveness of HMO internal quality assurance programs. Although PRO case-by-case review of HMO quality of care is mandated, PRO review of HMOs' internal quality assurance programs is optional and most HMOs have chosen not to subject their programs to PRO review (355). The increasing enrollment of Medicare beneficiaries in risk-based HMOs in recent years (355) makes it all the more important to extend any Medicare HDIT quality assurance efforts (including PRO review) to these plans.[26]

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24 The number of Medicare beneficiaries enrolled in risk-based HMOs more than doubled between 1985 and 1990 (from 383,480 to 1,238,479) (355). See 42 CFR part 417 for a description of Medicare contracts with risk-based HMOs/CMPs.

25 Public Law 99-509 amended this provision, allowing HMOs to contract with organizations other than PROS for quality review and changing the effective date of mandated PRO review to April 1,1987. As of September 1990, despite the allowance of Public Law 99-509, all risk-based HMO quality of care review was being conducted by 30 Medicare PROS (355).

26 HCFA has recently proposed major changes in the PRO review process for HMO/CMP enrollees. The changes, which would be implemented sometime during 1992 or 1993 if approved, include a move away from inpatient hospital claims review toward a more comprehensive review of *all care* delivered over a 12-month period for a random sample of enrollees (46). HCFA has also proposed tbat PROS conduct a more focused review of records of deceased beneficiaries (46).