

APPENDIXES

Appendix A

METHOD OF THE STUDY

History of the Project

The origins of this study lie in the passage of the Medicare Catastrophic Coverage Act of 1988 and its subsequent repeal in 1989. As part of a broad coverage expansion that would have extended Medicare coverage to outpatient prescription drugs, that act would have resulted in greater coverage of outpatient immunosuppressive drugs (now limited to coverage for only 1 year), and it would have established a home intravenous drug therapy benefit. With the repeal of that act, these two more specific coverage expansions once again became issues before Congress.

In April of 1990, the Senate Committee on Finance asked the Office of Technology Assessment (OTA) to revisit these two topics and the relevant coverage and payment issues they involve. The proposed assessment was approved by OTA's congressional Technology Assessment Board in June 1990 and begun the following month. The assessment was conducted in two parts leading to two separate reports, one on immunosuppressive drugs and one on home intravenous drugs and other drugs infused at home.

Conduct of the Home Drug Infusion Therapy (HDIT) Study

During the fall of 1990 and the first 6 months of 1991, OTA staff reviewed the literature on HDIT and interviewed experts in home care, medicine, intravenous nursing, clinical pharmacy, and infusion equipment manufacturing. Project staff also met several times with individuals at the Health Care Financing Administration to learn from their experience with HDIT coverage after the Medicare Catastrophic Coverage Act, and with several private insurance company representatives regarding the experiences of private payers with HDIT.

In the course of the interviews and literature review, it became clear that objective and detailed information on many aspects of HDIT was incomplete or lacking entirely. To gain a more comprehensive understanding of the therapy and the industry that provides it, OTA made a number of site visits to providers. The organizations visited included a spectrum of hospital-, pharmacy-, home health agency-, and specialty-company-based HDIT programs. A list of these organizations appears at the end of this appendix. In addition, staff met with provider representatives at OTA and held extensive telephone interviews. OTA staff also met with individuals from

organizations that include HDIT providers among their members.

OTA also requested detailed data on such aspects as provider structure and summary patient information from the providers contacted. Few providers were able to supply these data, lending insights into the information difficulties a Medicare policy might face.

Most major OTA studies have a panel of outside experts chosen to advise OTA staff on the study and ensure that all significant points of view are represented. This study was originally intended to be performed in coordination with an ongoing study of drug research and development, with the same advisory panel. It transpired, however, that the two studies had little directly in common, and the advisory panel for the earlier study proved inappropriate for the existing study. Because of the short timeframe anticipated for this study, it also proved infeasible to appoint a separate advisory panel at the point for the current study.

To ensure that sufficient expert advice was obtained and that all viewpoints were represented, OTA staff took great care to involve a variety of outside persons in the review of the draft material. A preliminary draft was sent to nearly 100 experts in the field, including HDIT providers, manufacturers, health professional and patient organizations, health care payers, researchers, and others with interest and knowledge in the area of HDIT for their review and comment. Fifteen representatives of the major organizations concerned with HDIT met at OTA for a public discussion of the draft on September 10, 1991 (see p. v of this report). The final draft, incorporating revisions based on reviewers' comments and discussion at the public meeting, was transmitted to the Technology Assessment Board in October 1991.

Contractors providing material to OTA for this study were:

Julia T. Ostrowsky, Chicago, IL, survey of Medicare Part B carriers regarding coverage of and payment for drugs used in infusion pumps under the durable medical equipment (DME) benefit, conducted February 1991.

Thomas W. Grannemann, Lexington, MA, "Incentives and Behavioral Responses to Alternative Payment Methods for Home Intravenous and Immunosuppressive Drug Therapies Under the Medicare Program," prepared under contract to the Office of Technology Assessment, February 1991.

OTA Site Visits to HDIT Providers

Anne Arundel General Hospital Outpatient IV Therapy
Services Program

Annapolis, MD
November 1990

Caremark
Columbia, MD
August 21, 1990

Handmaker Home Health Services, Inc.
Tucson, AZ
May 2, 1991

Infusion Care
Columbia, MD
August 2, 1990

Jefferson County Department of Health
Birmingham, AL
November 1, 1990

HMSS, Inc.
Phoenix, AZ
May 3, 1991

New England Critical Care
Columbia, MD
August 21, 1990

Jefferson (Hospital) Home Infusion Service
Philadelphia, PA
September 20, 1990

University Medical Center Home Health Services, Inc.
Tucson, AZ
May 2, 1991

Vital Care, Inc.
Livingston, AL
November 2, 1990

Visiting Nurses Association of Washington
Washington, DC
February 4, 1991

Provider Visits to OTA

ABEL Health Management Services, Inc.
November 9, 1990

Arlington Cancer Center
April 25, 1991

Kimberly Quality Care
January 23, 1991