

The Office of Technology Assessment (OTA) originally undertook this study of Medicare payment for recombinant erythropoietin as part of a larger assessment of Medicare payment for prescription drugs. In connection with the Medicare Catastrophic Coverage Act of 1988 (Public Law 100-360), the House Committees on Energy and Commerce and on Ways and Means and the Senate Committee on Finance jointly requested OTA to examine alternative payment policies for the prescription drug benefit added by the Act. The Senate Special Committee on Aging also requested the study. In April 1989, OTA's Technology Assessment Board (TAB) approved an OTA study on prescription drug payment to start in July 1989. In the context of the larger study, in May 1989 the House Committee on Ways and Means, Subcommittee on Health also asked OTA to study payment strategies that Medicare might apply to recombinant erythropoietin, which was about to be approved by the Food and Drug Administration.

The advisory panel for the parent assessment, "Medicare's Prescription Drug Benefit: Alternative Payment Policies," which consisted of 22 people from pharmaceutical manufacture, distribution, and dispensing; medicine; consumer advocacy; economics; law; and insurance, initially provided guidance for the study on recombinant erythropoietin (see app. C). At its meeting in September 1989, the advisory panel reviewed background material prepared by OTA staff on policy issues related to Medicare payment of recombinant erythropoietin and suggested additional sources of information and payment policies to consider.

During the fall and winter of 1989, OTA staff met with representatives of companies manufacturing recombinant erythropoietin; staff of Federal agencies responsible for policies related to recombinant erythropoietin, chiefly the Food and Drug Adminis-

tration and the Health Care Financing Administration; and health services researchers with expertise on Medicare's End-Stage Renal Disease Program. OTA staff also visited two dialysis centers, one hospital-based and one free-standing, and discussed issues of recombinant erythropoietin with their nephrologists. In addition, OTA staff reviewed the published and unpublished literature on the efficacy and safety of recombinant erythropoietin and on economic topics pertaining to payment options. The Food and Drug Administration (FDA), the Health Care Financing Administration, and the Department of Veterans Affairs provided information on their relevant regulations and guidelines.

In February 1990, OTA convened a workshop to discuss the draft report. Workshop participants included people from the following fields: manufacture of recombinant erythropoietin, wholesale distribution of pharmaceuticals, provision of dialysis services, nephrology, consumer advocacy, economics, Medicare policy, FDA policy, consumer advocacy, pharmacy administration, and law (See app. B). In addition to the workshop participants, the draft report was sent for review to members of the advisory panel for the broader study of Medicare's prescription drug benefit and to others from a range of disciplines and interests. During February and March 1990, OTA staff revised the report on the basis of the discussion at the workshop and on comments and additional material from reviewers. The staff prepared a final draft, which was submitted in late March 1990 to the Technology Assessment Board for its approval.

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**1**In March 1990, in light of Congress' previous repeal of the Medicare Catastrophic Coverage Act of 1988, OTA's Technology Assessment Board rescinded approval for the study "Medicare's Prescription Drug Benefit: Alternative Payment Policies."