

used to treat breast cancer), injectable anti-emetic drugs used to treat the nausea resulting from chemotherapy, infliximab used to treat rheumatoid arthritis, and rituximab used to treat non-Hodgkin's lymphoma.

## 2. Durable Medical Equipment (DME) Drugs

These are drugs that are administered through a covered item of DME such as a nebulizer or pump. Two of the most common drugs in this category are the inhalation drugs albuterol sulfate and ipratropium bromide.

## 3. Statutorily Covered Drugs and Other Drugs

Certain drugs are specifically covered by statute including: immunosuppressive drugs; hemophilia blood clotting factor; certain oral anti-cancer drugs; oral anti-emetic drugs; pneumococcal, influenza and hepatitis vaccines; antigens; erythropoietin for trained home dialysis patients; certain other drugs separately billed by end stage renal disease (ESRD) facilities (for example, iron dextran, vitamin D injections); and osteoporosis drugs.

## 4. Types of Providers

Types of providers and suppliers that are paid based on average wholesale price (AWP) for all or some of the Medicare covered drugs they furnish include: physicians, pharmacies, DME suppliers, hospital outpatient departments, and ESRD facilities.

## 5. Drugs Paid on a Cost or Prospective Payment Basis

Drugs paid on a cost or prospective payment basis that are generally outside of the scope of this proposed rule include: drugs furnished during an inpatient hospital stay (except clotting factor); drugs packaged under the outpatient prospective payment system (OPPS); drugs furnished by ESRD facilities whose payments are included in Medicare's composite rate; and drugs furnished by critical access hospitals, skilled nursing facilities (unless outside of a covered stay), comprehensive outpatient rehabilitation facilities, rural health facilities, and federally qualified health centers.

## B. Current Medicare Drug Spending

In 2002, the preliminary estimate of allowed charges for the approximately 450 drugs paid by Medicare carriers is \$8.4 billion. The majority of these expenditures were for drugs administered incident to a physician's service and drugs furnished in conjunction with DME. Spending growth for Medicare drugs has been

substantial. Medicare allowed charges for drugs were approximately \$3.3 billion in 1998. As indicated above, we estimate 2002 Medicare spending for drugs at approximately \$8.4 billion or nearly three times the 1998 levels or an average of 27 percent per year. Because during this time period Medicare fee-for-service enrollment grew by an average of only 1.4 percent per year, other factors such as price increases and additional utilization played a greater role in this expenditure growth. More than 77 percent of Medicare spending for drugs goes to oncologists and urologists for cancer drugs and pharmacies and other medical suppliers of DME drugs. Medicare spending for drugs billed by oncologists has more than tripled between 1998 and 2002 growing from \$1.2 billion to \$3.8 billion. Between 2001 and 2002, Medicare spending for drugs billed by oncologists increased by 41 percent. Growth in spending for the two highest expenditure DME drugs, albuterol and ipratropium bromide, has increased from \$393 million in 1998 to nearly \$1.0 billion in 2002.

Much of the current Medicare spending is concentrated in relatively few of the approximately 450 covered drugs. For example, of the \$8.4 billion for carrier paid drugs, 7 drugs account for 49 percent of spending (\$4.0 billion), 19 drugs account for 75 percent of spending (\$6.2 billion) and 33 drugs account for 86 percent of spending (\$7.1 billion). The top drug code, epoetin alpha (Q0136), accounts for 13 of carrier spending. Two prostate cancer drugs, lupron acetate for depot suspension (J9217) and goserelin acetate implant (J9202), combined, account for 14 of carrier paid drugs. Two generic drugs furnished via a covered item of DME, albuterol and ipratropium bromide, account for 13 percent of carrier drug spending.

Intermediaries and not carriers process ESRD facility claims for drugs paid outside the ESRD composite rate. In 2000, allowed charges for ESRD facilities for these drugs were \$1.4 billion for erythropoietin, \$0.1 billion for iron dextran, \$0.1 billion for vitamin D injections, and \$0.4 billion for all other separately billed drugs. Section 1881(b)(11)(B) of the Act provides a statutory formula to determine the payment amount for erythropoietin separately billed by ESRD facilities. The other drugs furnished and separately billed by ESRD facilities are paid 95 percent of the AWP under section 1842(o) of the Act.

## C. History of the Current Payment System

In the June 5, 1991 physician fee schedule proposed rule (56 FR 25792), we proposed that the drug payment limit be based on 85 percent of the national AWP of the drug. For very high volume drugs, we proposed that the drug payment limits be based on the estimated acquisition cost (EAC) of the drugs. The EAC was to be determined from survey data. We received many comments, primarily from oncologists, indicating that an 85 percent standard was inappropriate. In response to these comments, the 1992 physician fee schedule final rule established a payment limit based on the lower of 100 percent of AWP or the EAC. However, because of statistical sampling concerns generated by a lack of information on the variation in acquisition costs between low and high volume providers, the EAC was never implemented. Various legislative proposals were submitted to move away from payment based on 100 percent of AWP, including changing the percentage of AWP to a lower amount. In 1997, the Congress, responding in part to one of these proposals, amended the Act to limit payment for drugs not paid on a cost or prospective payment basis to the lower of the actual charge or 95 percent of AWP (section 1842(o)(1) of the Act as added by section 4556 of the Balanced Budget Act of 1997 (BBA 1997) (Pub. L. 105-33)). The statutory term, average wholesale price, is not defined in law or regulation. In creating payment limits for Medicare covered drugs, Medicare currently relies on the list AWP. The term "list AWP" will hereafter refer to the AWP published in commercial compendia such as Red Book, Price Alert, and Medispan.

## D. List AWP and Widely Available Market Prices

Numerous reports by the General Accounting Office (GAO), and the Office of Inspector General (OIG), as well as data collected by the Department of Justice (DOJ), discussed below, have indicated that 95 percent of list AWP reflected in published compendia is significantly higher than the prices that drug manufacturers, wholesalers, physician supply houses, specialty pharmacies, and similar entities actually charge to physicians and suppliers purchasing these drugs.

Differences between Medicare's payment based on 95 percent of list AWP and the widely available market prices creates what has been referred to as the "spread". The presence of a