

We are making the addition of these new CPT codes to the ASC list effective for services furnished on or after July 1, 2003 because we believe that were we not to add them in this final rule, we would limit beneficiary access to surgical procedures that can be appropriately performed in the ASC setting. If these codes are not payable under the ASC benefit, beneficiaries are limited to receiving the services that they describe in a hospital setting. Also, ASCs cannot receive a facility fee for these services under the Medicare ASC benefit if we do not add them to the list. Therefore, delay in adding these new surgical procedures to the ASC list is contrary to the public interest.

Also, it is impracticable not to add the applicable new CPT codes created from 1999 through 2003 until after we have received public comments, analyzed those comments, and issued a final rule. To do so could mean that the new CPT codes would not be made final under the ASC benefit until 2004, at the earliest.

For these reasons, we find good cause to waive the notice of proposed rulemaking and to issue this final rule with comment. We are providing a 60-day public comment period regarding the addition of the new CPT codes, designated by an "A*" in the addendum and the payment group to which these codes are assigned. We will respond to timely comments in the next final notice or final rule that we issue regarding the ASC benefit.

VII. Regulatory Impact Statement

A. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96-354), Section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). Our Office of the Actuary has prepared a fiscal impact estimate. As shown in the table below, for fiscal years 2003 through 2007, the cost to the Medicare program is estimated to be \$5

million per year. Therefore, this is not considered a major rule.

Fiscal year	Cost ¹
2003	\$5
2004	5
2005	5
2006	5
2007	5

¹ Cost in millions, rounded to the nearest 5 million.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6 to \$29 million in any 1 year. According to the small business associations, approximately 73 percent of all ASCs are considered small entities by having revenues of \$11.5 million or less. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. This rule does not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. This rule will not have an effect on the governments mentioned and the private sector costs will be less than the \$110 threshold.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This rule will not have a substantial effect on State or local governments.

B. Anticipated Effects

The entities affected by this final rule with comment period are Medicare certified ASCs and beneficiaries. No

other providers are affected. This rule will not affect state or local governments or the private sector other than ASCs. There are more than 3,000 ASCs currently certified by Medicare, nearly three-quarters of which fit the definition of a "small entity."

The result of this rule is to increase the number of ASC procedures approved for Medicare payment by approximately 300, thereby making more surgical services payable by Medicare in an ASC available to beneficiaries. ASCs will benefit from our expanding the list of Medicare approved ASC procedures because the number of services for which Medicare will pay a facility fee will increase as a result. Currently, if ASCs perform these procedures, Medicare does not allow payment of a facility fee. Our adding these codes to the ASC list also enables ASCs to serve a greater number of beneficiaries by being able to offer access to an increased number of surgical services. The number of claims for ASC services would increase. No specific provisions of this final rule have yet been implemented. If this final rule is not issued, beneficiaries would be denied access to approximately 300 surgical procedures in the ASC setting and this would limit beneficiary choice.

Some individuals have advocated the elimination of the ASC list on the basis that the decision regarding where to perform a procedure rests ultimately with the physician. These same individuals support payment of an ASC facility fee for any surgical procedure covered by Medicare in a clinic or hospital outpatient setting. The requirements for an ASC list are imposed by the statute, so we cannot adopt this recommendation.

ASCs that specialize in dermatology, gastroenterology, and orthopedics may object to our not adding certain procedures that we proposed in our June 1998 proposed rule. In particular, we are not adding procedures performed more than 50 percent of the time in a physician's office, procedures that are not appropriately or safely performed in an ambulatory setting, or procedures that would otherwise have met the criteria for inclusion on the ASC list except that they would be significantly overpaid in the lowest ASC payment group. We have determined that the adverse economic impact on the Medicare program that could result from a shift of such services to an ASC setting outweighs the potential negative reaction of these medical specialties.

ASCs that furnish extracorporeal shockwave lithotripsy (ESWL) services may also object to our not adding this procedure to the ASC list. However, as