

Individuals and States are not considered small entities. Therefore, no regulatory relief options are considered. A rule has a significant economic impact if it exceeds 3–5 percent of its total costs or revenues according to criterion set by the SBA. The statute exempts many small firms from this rulemaking, affording considerable relief to small entities. At most, small firms that are not exempt will incur an average of either \$69 per firm (\$7.1 million/102,704 firms) to contract out their claims filing, or purchase computer equipment at an average net cost of \$135 per firm (\$750 cost – \$615 savings.) Therefore, we expect the impact of this rulemaking to fall well below the SBA threshold.

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. As indicated above, this rule could have an impact on those small rural hospitals that bill Medicare and that do not meet one of the exceptions. However, we do not believe the impact is significant since the cost of compliance is relatively small (\$500 to \$1,000) and small rural hospitals may be able to qualify for the small provider exception. Therefore, no regulatory impact analysis is required as the impact on small rural hospitals is not significant.

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 an expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. This interim final rule with comment period will not have an impact on State, local, or tribal governments or on the private sector. Instead, the primary impact on State, local, or tribal governments, or the private sector will be that entities that must begin billing Medicare electronically as a result of the ASCA are likely to use that capability to also bill other payers (such as State, local, or tribal governments and the private sector).

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 interim final rule with comment period will not have a substantial effect on State or local governments for the reasons noted above.

B. Anticipated Effects

1. Effects on Beneficiaries, Physicians, Practitioners, Facilities, Suppliers, and Other Health Care Providers

The anticipated effects on Medicare's beneficiaries will be that additional attention and services may be provided by their health care physician because, for example, electronic billing should reduce administrative paperwork. (This assertion has been made by the medical community in numerous forums over the years, though documentation to this effect is not available.)

The anticipated effects on the entities required to bill electronically will reduce or eliminate paper in their administrative operations, realizing increased efficiencies and indeterminable savings. These savings may be increased by the fact that the Administrative Simplification provisions of HIPAA mandate a standard transaction for electronic claim submissions, and this will facilitate electronic claims submissions to all health care payers. At this time, we do not have additional data to estimate those savings to Medicare physicians, practitioners, facilities, suppliers, and other healthcare providers. As previously stated, there will be a cost incurred by those entities that cannot satisfy one of the exceptions and would be required to bill Medicare in electronic form.

2. Effects on the Medicare and Medicaid Programs

Implementation of this interim final rule with comment period will result in a savings to the Medicare program. If the FY 2004 projected paper claims submissions of 136.2 million (HHS FY 2004 Budget submission to the Congress and estimated electronic media claims rate), are reduced by half and we assume a savings of \$1.40 per claim as a result, the program could realize administrative savings of over \$95 million per year. (**Note:** The \$1.40 per claim savings is the CMS estimate of savings based upon a 1990 Industrial Engineering Study, contracted by CMS (then HCFA). The study documented that FI paper claims cost about \$3.30 more to process than electronic claims and, similarly, carrier paper claims cost about \$1.00 more to process than electronic claims. Weighing these differences by the 2004 workloads and

combining them yields the \$1.40 estimated per claim savings.)

We might expect similar types of savings for the States, which administer the Medicaid Program. That is, Medicare providers who become electronic billers due to ASCA may decide to begin billing Medicaid electronically as well. However, this would depend on which of the affected Medicare physicians, practitioners, facilities, suppliers, and other healthcare providers also bill Medicaid. Again, the fact that the Administrative Simplification provisions of HIPAA mandate a standard transaction for electronic claim submissions will facilitate electronic claims submissions to all health care payers.

C. Alternatives Considered

Section 3 of ASCA requires electronic claims submission by those who bill Medicare. There is little room for us to consider alternatives, though we expect that public comment may focus upon further definition regarding the mandatory waivers or regarding those "unusual cases" for which the Secretary may waive the mandatory electronic claims submission requirement.

D. Conclusion

As described above, this interim final rule with comment period establishes the requirements for implementing the statutory provisions under section 3 of the ASCA. The law requires, with few exceptions, that physicians, practitioners, facilities, suppliers, and other health care providers that bill Medicare must do so electronically. Coupled with the electronic standard transaction requirements under HIPAA, this rule facilitates greater administrative efficiencies for the Medicare program as well as for those that bill Medicare. There will be a cost incurred for those entities that are unable to meet one of the statutory exceptions, but we expect these initial costs to be offset by increased efficiencies and ongoing lower costs attributable to Medicare claims processing.

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget reviewed this regulation.

List of Subjects in 42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, CMS proposes to amend 42 CFR chapter VI part 424 as set forth below: