seeks comment on what additional legislative authorities, if any, would be necessary or appropriate to enable FDA to address this issue most effectively.

For interested parties who would like to submit comments on these issues or additional data from any well-conducted scientific studies, we are reopening the comment period of the June 1997 proposal for 30 days. If, after evaluating the comments received on this document, FDA believes that a warning statement on the labels of dietary supplements containing ephedrine alkaloids is necessary to protect the health of individuals consuming such products, the agency will move quickly to publish a final rule requiring the appropriate warning statement and to take any other action we determine to be appropriate.

II. How to Submit Comments

Interested persons may submit to the Dockets Management Branch (see ADDRESSES) written or electronic comments. Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Identify all comments with the docket numbers found in brackets in the heading of this document. You may review received comments in the Dockets Management Branch office between 9 a.m. and 4 p.m., Monday through Friday.

III. References

The following references have been placed on display in the Dockets Management Branch (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.


William K. Hubbard,
Associate Commissioner for Policy and Planning.

DEPARTMENT OF AGRICULTURE
Forest Service
36 CFR Part 219
RIN 0596–AB66
National Forest Service Land and Resource Management Planning
AGENCY: Forest Service, USDA.
ACTION: Notice; extension of public comment period.
SUMMARY: Notice is hereby given that the public comment period for the proposed rule for National Forest System Land and Resource Management Planning, published in the Federal Register on December 6, 2002 (67 FR 72770), is being extended. The original comment period end date was March 6, 2003.
DATES: Comments on the proposed rule must be received in writing, on or before the new deadline of April 7, 2003.
ADDRESSES: Comments may be sent to USDA FS Planning Rule, Content Analysis Team, PO Box 8359, Missoula, MT 59807; via email to planning_rule@fs.fed.us; or by facsimile to Planning Rule Comments at (406) 329–3556. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying.
FOR FURTHER INFORMATION CONTACT: Jody Sutton, Content Analysis Team Program Coordinator, Forest Service, (801) 517–1023.
SUPPLEMENTARY INFORMATION: The Diversity Options Workshop was held February 18–20, 2003, to discuss the approaches to implementing the National Forest Management Act (NFMA) diversity requirement in the proposed rule; address strengths and weaknesses of the two diversity options in the proposed rule; and to discuss any additional options for implementing the NFMA diversity requirement.
Proceedings from the Diversity Options Workshop are expected to be posted on World Wide Web at www.fs.fed.us/ecm/nfma by March 17, 2003.

Bov B. Eav,
Acting Chief.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services
42 CFR Part 412
[CMS–1243–P]
RIN 0938–AM41
Medicare Program; Proposed Change in Methodology for Determining Payment for Extraordinarily High-Cost Cases (Cost Outliers) Under the Acute Care Hospital Inpatient Prospective Payment System
AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.
ACTION: Proposed rule.
SUMMARY: In this proposed rule, we are proposing to change the methodology for determining payments for extraordinarily high-cost cases (cost outliers) made to Medicare-participating hospitals under the acute care hospital inpatient prospective payment system. Under the existing outlier methodology, the cost-to-charge ratios from hospitals’ latest settled cost reports are used in determining a fixed-loss amount cost outlier threshold. We have become aware that, in some cases, hospitals’ recent rates of charge...
increases greatly exceed their rates of cost increases. This disparity results in their cost-to-charge ratios being set too high, which in turn results in an overestimation of their current costs per case. Therefore, we need to make revisions to our outlier payment methodology to correct those situations in which hospitals would otherwise receive overpayments for outlier cases due to excessive charge increases.

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on April 4, 2003.

ADDRESSES: Mail written comments (one original and three copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1243–P, PO Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be timely received in the event of delivery delays. If you prefer, you may deliver (by hand or courier) your written comments (one original and three copies) to one of the following addresses: Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building.

A stamp-in clock is available for commenters wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late.

In commenting, please refer to file code CMS–1243–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission or e-mail.

For information on viewing public comments, see the beginning of the SUPPLEMENTARY INFORMATION section.

For comments that relate to information collection requirements, mail a copy of comments to the following addresses:

Centers for Medicare & Medicaid Services,


SUPPLEMENTARY INFORMATION: Inspection of Public Comments: Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244. Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, call telephone number: (410) 786–9994.

Availability of Copies and Electronic Access

Copies: To order copies of the Federal Register containing this document, send your request to: New Orders, Superintendent of Documents, PO Box 371954, Pittsburgh, PA 15250–7954. Specify the document issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 (or toll-free at 1–888–293–6498) or by faxing to (202) 512–2250. The cost for each copy is $10. As an alternative, you can view and photocopy the Federal Register document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the Federal Register.

This Federal Register document is also available from the Federal Register online database through GPO Access, a service of the U.S. Government Printing Office. The Web site address is: http://www.access.gpo.gov/nara/index.html.

I. Background

A. Description of the Acute Care Hospital Inpatient Prospective Payment System (IPPS)

Section 1886(d) of the Social Security Act (the Act) sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. This payment system is referred to as the acute care hospital inpatient prospective payment system (IPPS). Under the IPPS, each case is categorized into a diagnosis-related group (DRG). Each DRG has a payment weight assigned to it, based on the average resources used to treat Medicare patients in that DRG.

The base payment rate is divided into a labor-related share and a nonlabor-related share. The labor-related share is adjusted by the wage index applicable to the area where the hospital is located, and if the hospital is located in Alaska or Hawaii, the nonlabor-related share is adjusted by a cost-of-living adjustment factor. This base payment rate is multiplied by the DRG relative weight.

If the hospital treats a high-percentage of low-income patients, it receives a percentage add-on payment applied to the DRG-adjusted base payment rate. This add-on payment, known as the disproportionate share hospital (DSH) adjustment, provides for a percentage increase in Medicare payment for hospitals that qualify under either of two statutory formulas designed to identify hospitals that serve a disproportionate share of low-income patients. For qualifying hospitals, the amount of this adjustment may vary based on the outcome of the statutory calculation.

Also, if the hospital is an approved teaching hospital it receives a percentage add-on payment for each case paid through the IPPS. This add-on payment, known as the indirect medical education (IME) adjustment, varies depending on the ratio of residents-to-beds under the IPPS for operating costs and according to the ratio of residents-to-average daily census under the IPPS for capital costs.

Additional payments may be made for cases that involve new technologies that have been approved for special add-on payments. To qualify, a new technology must demonstrate that it is a substantial clinical improvement over technologies otherwise available, and that, absent an add-on payment, it would be inadequately paid under the regular DRG payment.

Finally, for particular cases that are unusually costly, known as outlier cases (discussed below), the IPPS payment is increased. This additional payment is designed to protect the hospital from large financial losses due to unusually expensive cases. Any outlier payment due is added to the DRG-adjusted base payment rate, plus any DSH, IME, and new technology add-on adjustments.

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient hospital services “in accordance with a prospective payment system established by the Secretary.” The basic methodology for determining
capital prospective payments is set forth in our regulations at §§ 412.308 and 412.312. Under the capital prospective payment system, payments are adjusted by the same DRG for the case as they are under the operating IPPS. Similar adjustments are also made for IME and DSH as under the operating IPPS. Hospitals also may receive an outlier payment for those cases that qualify.

**B. Payment for Outlier Cases**

1. General

Section 1886(d)(5)(A) of the Act provides for payments in addition to the basic prospective payments for cases incurring extraordinarily high costs. To qualify for outlier payments, a case must have costs above a fixed-loss cost threshold amount (a dollar amount by which the costs of a case must exceed payments in order to qualify for outliers).

Hospital-specific cost-to-charge ratios are applied to the covered charges for the case to determine whether the costs of the case exceed the fixed-loss outlier threshold. Payments for eligible cases are then made based on a marginal cost factor, which is a percentage of the costs above the threshold. For Federal fiscal year (FY) 2003, the existing fixed-loss outlier threshold is $33,560.

The actual determination of whether a case qualifies for outlier payments takes into account both operating and capital costs and DRG payments. That is, the combined operating and capital costs of a case must exceed the fixed-loss outlier threshold to qualify for an outlier payment. The operating and capital costs are computed separately by multiplying the total covered charges by the operating and capital cost-to-charge ratios. The estimated operating and capital costs are compared with the fixed-loss threshold after dividing that threshold into an operating portion and a capital portion (by summing the operating and capital ratios and determining the proportion of that total comprised by the operating and capital ratios, and then applying these percentages to the fixed-loss threshold).

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### Operating Portion

<table>
<thead>
<tr>
<th>National Large Urban Standardized Amounts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Labor-related ................................ $3,022.60</td>
</tr>
<tr>
<td>Nonlabor-related ................................ $1,228.60</td>
</tr>
<tr>
<td>San Francisco MSA Wage Index .............. 1.4142</td>
</tr>
<tr>
<td>IME Operating Adjustment Factor ........... 0.0744</td>
</tr>
<tr>
<td>DSH Operating Adjustment Factor ........... 0.1413</td>
</tr>
<tr>
<td>DRG 286 Relative Weight ...................... 1.2679</td>
</tr>
<tr>
<td>Labor-Related Portion ......................... 0.711</td>
</tr>
<tr>
<td>Nonlabor-Related Portion ..................... 0.289</td>
</tr>
</tbody>
</table>

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Federal Payment for Operating Costs = DRG Relative Weight × (Labor-Related Large Urban Standardized Amount × San Francisco MSA Wage Index) + Nonlabor-Related National Large Urban Standardized Amount) × (1 + IME + DSH): 2.0937 × [(3,022.60 × 1.4142) + $1,228.60] × (1 + 0.0744 + 0.1413) = $14,007.26

#### Step 1:
Determine the Federal operating and capital payment with IME and DSH adjustment based on the following values:

- **Labor-Related Portion**: $3,022.60
- **Nonlabor-Related Portion**: $1,228.60
- **San Francisco MSA Wage Index**: 1.4142
- **IME Operating Adjustment Factor**: 0.0744
- **DSH Operating Adjustment Factor**: 0.1413
- **DRG 286 Relative Weight**: 1.2679

#### Step 2:
Determine operating and capital costs from billed charges by applying the respective cost-to-charge ratios.

- **Billed Charges**: $150,000
- **Operating Costs**: $75,000
- **Capital Cost-to-Charge Ratio**: 0.06

#### Step 3:
Determine outlier threshold.

- **Fixed Loss Threshold**: $33,560

#### Step 4:
Determine outlier payment.

- **Marginal Cost Factor**: 0.80
- **Outlier Payment**: $32,192

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Federal Payment for Capital Costs = DRG Relative Weight × Federal Capital Rate × Large Urban Add-On × Geographic Adjustment Factor × (1 + IME + DSH): 2.0937 × $407.01 × 1.03 × 1.2679 × (1 + 0.0243 + 0.0631) = $1,210.12

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The thresholds are also adjusted by the area wage index (and capital geographic adjustment factor) before being compared to the operating and capital costs of the case. Finally, the outlier payment is equal to 80 percent of the combined operating and capital costs in excess of the fixed-loss threshold (90 percent for burn DRGs).

The following example simulates the outlier payment for a case at a generic hospital that receives IME and DSH payments in San Francisco, California (a large urban area). The patient was discharged after October 1, 2002, and the hospital incurred Medicare-covered charges of $150,000. The DRG assigned to the case was DRG 286, Adrenal and Pituitary Procedures, with a FY 2003 relative weight of 2.0937. There is no new technology add-on payment for the case.

**Step 1:**
Determine the Federal operating and capital payment with IME and DSH.
ratio and, effective with cost reporting periods beginning on or after October 1, 1991, the capital cost-to-charge ratio used to adjust covered charges are computed annually by the intermediary for each hospital based on the latest available settled cost report for that hospital and charge data for the same time period as that covered by the cost report.

In the September 30, 1988 final rule with comment period published in the Federal Register (53 FR 38503), we initiated the use of hospital-specific cost-to-charge ratios to determine hospitals' costs for assessing whether a case qualifies for payment as a cost outlier. Prior to that change, we determined the cost of discharges based on a nationwide cost-to-charge ratio of 60 percent. We indicated at the time that the use of hospital-specific cost-to-charge ratios is essential to ensure that outlier payments are made only for cases that have extraordinarily high costs, and not merely high charges.

Currently, cost-to-charge ratios are determined using the most recent settled cost report for each hospital. At the end of the cost reporting period, Medicare charges from all claims are accumulated through the Provider Statistical and Reimbursement Report (PS&R). The PS&R contains data such as the number of discharges and the actual charges from each hospital. The hospital also submits a cost report to its fiscal intermediary, which is used to determine total allowable inpatient Medicare costs. Once all these data are available, the fiscal intermediary then determines the cost-to-charge ratio for the hospital by using charges from the PS&R and costs from the cost report.

Statewide average cost-to-charge ratios are used in those instances in which a hospital's operating or capital cost-to-charge ratios fall outside reasonable parameters. CMS sets forth these parameters and the statewide cost-to-charge ratios in the annual notices of prospective payment rates that are published by August 1 of each year in accordance with §412.8(b). For FY 2003, those parameters are set at operating cost-to-charge ratios lower than 0.194 or greater than 1.258, or capital cost-to-charge ratios lower than 0.012 or greater than 0.163. These ranges represent 3.0 standard deviations (plus or minus) from the geometric mean of cost-to-charge ratios for all hospitals.

The Congress intended that outlier payments would be made only in situations where the cost of care is extraordinarily high in relation to the average cost of treating comparable conditions or illnesses. Under our existing outlier methodology, if hospitals' charges are not sufficiently comparable in magnitude to their costs, the legislative purpose underlying the outlier regulations is thwarted.

Recent analysis indicates that some hospitals have taken advantage of two vulnerabilities in our methodology to maximize their outlier payments. One vulnerability is the time lag between the current charges on a submitted bill and the cost-to-charge ratio taken from the most recent settled cost report. The second vulnerability, in some cases, is that hospitals may increase their charges so far above costs that their cost-to-charge ratios fall below 3 standard deviations from the geometric mean of cost-to-charge ratios and a higher statewide average cost-to-charge ratio is applied. In this proposed rule, we are proposing to implement new regulations to ensure outlier payments are paid only for truly high-cost cases.

Because the fixed-loss threshold is determined based on hospitals' historical charge data, hospitals that have been inappropriately maximizing their outlier payments have caused the threshold to increase dramatically for FY 2003. As illustrated by the table below, the cost outlier threshold increased by 80 percent from $9,700 in FY 1997 to $17,550 in FY 2001. In addition, the cost outlier threshold increased by 91 percent from $17,550 in FY 2001 to $33,560 in FY 2003. The table also demonstrates, for the three most recent years, the level at which the threshold would have to have been set in order to result in outlier payments equal to 5.1 percent of total DRG payments (absent further behavioral responses by hospitals).

<table>
<thead>
<tr>
<th>Fiscal year</th>
<th>Outlier percentage</th>
<th>Payments in excess of target of 5.1%* (in billions of dollars)</th>
<th>Outlier threshold</th>
<th>Threshold that would have paid out 5.1%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1997</td>
<td>5.5</td>
<td>0.3</td>
<td>$9,700</td>
<td>****</td>
</tr>
<tr>
<td>1998</td>
<td>6.5</td>
<td>1.0</td>
<td>11,050</td>
<td>****</td>
</tr>
<tr>
<td>1999</td>
<td>7.6</td>
<td>1.8</td>
<td>11,100</td>
<td>****</td>
</tr>
<tr>
<td>2000</td>
<td>7.6</td>
<td>1.8</td>
<td>14,050</td>
<td>$21,825</td>
</tr>
<tr>
<td>2001</td>
<td>7.7</td>
<td>1.9</td>
<td>17,550</td>
<td>26,200</td>
</tr>
<tr>
<td>2002</td>
<td>6.9</td>
<td>1.6</td>
<td>21,025</td>
<td>30,525</td>
</tr>
<tr>
<td>2003</td>
<td>5.1</td>
<td>N/A</td>
<td>33,560</td>
<td>****</td>
</tr>
</tbody>
</table>

*All payments are estimated and reflect operating payments only (not capital payments).

II. Provisions of this Proposed Rule

A. Updating Cost-to-Charge Ratios

Currently, we use the most recent settled cost report when determining cost-to-charge ratios for hospitals. The covered charges on bills submitted for payment during FY 2003 are converted to costs by applying a cost-to-charge ratio from cost reports that began in FY 2000 or, in some cases, FY 1999. These covered charges reflect all of a hospital's charge increases to date, in particular those that have occurred since FY 2000 and are not reflected in the FY 2000 cost-to-charge ratios. If the rate-of-charge increases since FY 2000 exceeds the rate of the hospital's cost increases during that time, the hospital's cost-to-charge ratio based on its FY 2000 cost report will be too high, and applying it to current charges will overestimate the hospital's costs per case during FY 2003. Overestimating costs may result in some cases qualifying for outlier payments that, in actuality, are not high cost cases.

Using the Medicare Provider Analysis and Review (MedPAR) file data from FY 1999 to FY 2001, we found 123 hospitals whose percentage of outlier payments relative to total DRG payments increased by at least 5 percentage points over that period, and whose case-mix (the average DRG relative weight value for all of a hospital's Medicare cases) adjusted charges increased at a rate at or above the 95th percentile rate of charge increase for all hospitals (46.63 percent) over the same period. We adjusted for case-mix because a hospital's average charges per case would be expected to change from one year to the next if the
hospital were treating new or different types of cases.

Because we use settled cost reports to compute hospitals’ cost-to-charge ratios, the recent dramatic increases in charges for these hospitals are not reflected in their cost-to-charge ratios. For example, among these 123 hospitals, the mean rate of increase in charges was 70 percent. Meanwhile, cost-to-charge ratios for these hospitals, which were based upon cost reports from prior periods, declined by only 2 percent.

Because a hospital has the ability to increase its outlier payments during this time lag through dramatic charge increases, in this proposed rule we are proposing new regulations at §412.84(i)(1) that would allow fiscal intermediaries to use more up-to-date data when determining the cost-to-charge ratio for each hospital. As mentioned above, currently fiscal intermediaries use the hospital’s most recent settled cost report. We are proposing to revise our regulations to specify that intermediaries will use either the most recent settled or the most recent tentative settled cost report, whichever is from the later cost reporting period.

Hospitals must submit their cost reports within 5 months after the end of their fiscal year. CMS makes a decision to accept a cost report within 30 days. Once the cost report is accepted, CMS makes a tentative settlement of the cost report within 60 days. The tentative settlement is a cursory review of the filed cost report to determine the amount of payment to be paid to the hospital if an amount is due on the as-filed cost report. After the cost report is tentatively settled, it can take 12 to 24 months, depending on the type of review or audit, before the cost report is final-settled. Thus, using cost-to-charge ratios from tentative settled cost reports, as we are proposing in this proposed rule, would reduce the time lag for updating cost-to-charge ratios by a year or more.

However, even the later ratios calculated from the tentative settled cost reports would overestimate costs for hospitals that have continued to increase charges much faster than costs during the time between the tentative settled cost report period and the time when the claim is processed. That is, even though we are proposing to reduce the lag in time by proposing to revise the regulations to use the latest tentative settled cost report, rather than the latest settled cost report, if it is from a later cost reporting period, there would still be a lag of 1 to 2 years during which a hospital’s charges may still increase faster than costs. Therefore, we are proposing to add a new provision to the regulations at §412.84(i). Under this proposed provision, in the event more recent charge data indicate that a hospital’s charges have been increasing at an excessive rate (relative to the rate of increase among other hospitals), CMS would have the authority to direct the fiscal intermediary to change the hospital’s operating and capital cost-to-charge ratios to reflect the high charge increases evidenced by the later data. In addition, we are proposing to allow a hospital to contact its fiscal intermediary to request that its cost-to-charge ratios, otherwise applicable under §412.84(i), be changed if the hospital presents substantial evidence that the ratios are inaccurate. Any such requests would have to be approved by the CMS Regional Office with jurisdiction over that fiscal intermediary.

B. Statewide Averages

As hospitals raise their charges faster than their costs increase, over time their cost-to-charge ratios will decline. If hospitals continue to increase charges at a faster rate than their costs increase over a long period of time, or if they increase charges at extreme rates, their cost-to-charge ratios may fall below the range considered reasonable under the regulations (0.194 for operating cost-to-charge ratios and 0.012 for capital cost-to-charge ratios in FY 2003 (67 FR 50125)), and, per current regulations at §412.84(h), their fiscal intermediaries will assign a hospital a statewide average cost-to-charge ratio. These statewide averages are generally considerably higher than the threshold. Therefore, under existing regulations, these hospitals benefit from an artificially high ratio being applied to their already high charges. Furthermore, hospitals can continue to increase charges faster than costs, without any further downward adjustment to their cost-to-charge ratios.

For example, in a 3-year span, one hospital was found to have an increase in charges of 60 percent from FY 1999 to FY 2000, 35 percent from FY 2000 to FY 2001, and 13 percent from FY 2001 to FY 2002. This hospital’s actual operating cost-to-charge ratio for FY 2003 was 0.093. Because this number is below the threshold of 0.194, the fiscal intermediary assigned this urban California hospital the statewide average cost-to-charge ratio of 0.328 (from Table 8A of the August 1, 2002 final rule, 67 FR 50263). In this case, receiving the statewide average cost-to-charge ratio increased the hospital’s estimated costs per case far above the estimate using the actual ratio, leading to substantially higher outlier payments to the hospital as a result of this policy.

In December 2002, we issued Program Memorandum A–02–122 requesting that fiscal intermediaries identify all hospitals receiving the statewide average operating or capital cost-to-charge ratio because their cost-to-charge ratios fell below the floor of reasonable parameters. We received a list of 43 hospitals that were assigned the statewide average operating cost-to-charge ratio and 14 hospitals that were receiving the statewide average capital cost-to-charge ratio. Three hospitals were found on both lists. Prior to application of the statewide average cost-to-charge ratios, the average actual operating cost-to-charge ratio for the 43 hospitals was 0.164, and the average actual capital cost-to-charge ratio for the 14 listed hospitals was 0.008. In contrast, the statewide average operating cost-to-charge ratio for the 43 hospitals was 0.3425 and the statewide average capital cost-to-charge ratio for the 14 hospitals was 0.035.

Because of hospitals’ ability to increase their charges to lower their cost-to-charge ratios in order to be assigned the statewide average, we are proposing to remove the current requirement in our regulations specifying that a fiscal intermediary will assign a hospital the statewide average cost-to-charge ratio when the hospital has a cost-to-charge ratio that falls below the floor. We are proposing that hospitals would receive their actual cost-to-charge ratios, no matter how low their ratios fall.

We are proposing that statewide average cost-to-charge ratios would still apply in those instances in which a hospital’s operating or capital cost-to-charge ratio exceeds the upper threshold. Cost-to-charge ratios above this range are probably due to faulty data reporting or entry, and should not be used to identify and pay for outliers. In addition, hospitals that have not yet filed their first Medicare cost reports with their fiscal intermediaries would still receive the statewide average cost-to-charge ratios.

C. Reconciling Outlier Payments Through Settled Cost Reports

Under the IPPS, hospitals submit a bill for each Medicare patient stay for which they expect a payment from Medicare. The bill includes information needed to: (1) Classify the case to a DRG; (2) determine whether the case was a transfer; (3) identify whether a new technology eligible for add-on payments was involved; and (4) calculate the costs of a case to determine whether it is eligible for an outlier
payment or a new technology add-on payment. This latter calculation is based on the covered charges reported on the bill, which, as discussed above, are also used to estimate the covered costs of the case by applying the cost-to-charge ratio.

The information from the bill is processed through the fiscal intermediary’s claims processing system to determine the payment amount for each case. Unless a hospital qualifies for periodic interim payments under § 412.116(b), payment is made on the basis of the actual amount determined for each bill processed. For hospitals that qualify for periodic interim payments, the fiscal intermediary estimates a hospital’s IPPS payments and makes biweekly payments equal to \(\frac{1}{2}\) of the total estimated amount of payment for the year. However, outlier payments are not made on an interim basis, but are made on a claim-by-claim basis (even for hospitals that qualify for interim payments under § 412.116(b)), and generally represent final payment (§ 412.116(e)).

An exception to this finality is the provision for medical review of a sample of outlier cases and for adjustments to be made to covered charges for any services that are found to be noncovered (§ 412.84(d)). In situations where a pattern of inappropriate utilization by a hospital is found, all outlier cases from that hospital may be subject to prepayment medical review (§ 412.84(c)).

CMS has generally limited the situations in which outlier payments may be reopened. This is in contrast to payments under the IME adjustment and the DSH adjustment, both of which are routinely adjusted when hospitals’ cost reports are settled to reflect updated data such as the number of residents or patient days during the actual cost reporting period. With respect to outliers, it has been CMS’s policy that payment determinations are made on the basis of the best information available at the time a claim is processed and are not revised, upward or downward, based upon updated data.

As stated earlier in this preamble, we are increasingly aware that some hospitals have taken advantage of the current outlier policy by increasing their charges at extremely high rates, knowing that there would be a time lag before their cost-to-charge ratios would be adjusted to reflect the higher charges. The steps we are proposing in this proposed rule to direct fiscal intermediaries to recalculate cost-to-charge ratios using the most recent tentative settled cost reports (and in some cases, even later data) and using actual rather than statewide average ratios for hospitals that have cost-to-charge ratios that are more than 3.0 standard deviations below the geometric mean cost-to-charge ratio, would greatly reduce the opportunity for hospitals to manipulate the system to maximize outlier payments. However, they would not completely eliminate all such opportunity. A hospital would still be able to dramatically increase its charges by far above the rate of increase in costs during any given year. This possibility is of great concern, given the recent findings that some hospitals that have been able to receive large outlier payments by doing just that.

Therefore, we are proposing to add a provision to our regulations to provide that outlier payments will become subject to adjustment when hospitals’ cost reports are settled (proposed § 412.84(ii)(2)). Payments would be processed throughout the year using operating and capital cost-to-charge ratios based on the best information available at that time. When the cost report is settled, any reconciliation of outlier payments by fiscal intermediaries would be based on operating and capital cost-to-charge ratios calculated based on a ratio of costs to charges computed from the cost report and charge data determined at the time the cost report coinciding with the discharge is settled.

This process would require some degree of recalculating outlier payments for individual claims. It is not possible to distinguish, on an aggregate basis, how much a hospital’s outlier payments would change due to a change in its cost-to-charge ratios. This is because, in the event of a decline in a ratio, some cases would no longer qualify for any outlier payments while other cases would qualify for lower outlier payments. Therefore, the only way to accurately determine the net effect of a decrease in cost-to-charge ratios on a hospital’s total outlier payments is to assess the impact on a claim-by-claim basis. We are still assessing the impact of this adjustment to reflect the time value of money in the case of underpayments. This adjustment would also apply in cases where outlier payments were underpaid to the hospital. In those cases, the adjustment would result in additional payments to hospitals. Any adjustment would be based upon a widely available index to be established in advance by the Secretary, and would be applied from the midpoint of the cost reporting period to the date of reconciliation (or when additional payments are issued, in the case of underpayments). This adjustment to reflect the time value of a hospital’s outlier payments would ensure that the outlier payment received by the hospital at the time its cost report is settled appropriately reflects the hospital’s true costs of providing the care.

This adjustment is also intended to account for the unique susceptibility of outlier payments to manipulation. Hospitals set their own level of charges and are able to change their charges, without review by their fiscal intermediaries. As outlined above, changes in charges directly affect the level of outlier payments. This lack of fiscal intermediary review of a factor affecting a hospital’s payments is in contrast to other IPPS adjustments, such as the IME adjustment or the DSH adjustment, where the fiscal intermediary must agree to a change to the determining factor (the resident-to-
bed ratio or the share of low-income patients, respectively).

Under section 1886(d)(5)(A)(iv) of the Act, outlier payments for any year must be projected to be not less than 5 percent nor more than 6 percent of the total estimated operating DRG payments plus outlier payments. Section 1886(d)(3)(B) of the Act requires the Secretary to reduce the average standardized amounts by a factor to account for the estimated proportion of total DRG payments made to outlier cases. Despite the fact that each individual hospital’s outlier payments may be subject to adjustment when the cost report is settled, we continue to believe that the fixed-loss outlier threshold should be based on projected payments using the latest available historical data without retroactive adjustments, either mid-year or at the end of the year, to ensure that actual outlier payments are equal to 5.1 percent of total DRG payments. That is, the above proposed change is intended only to allow for use of the actual cost-to-charge ratio from the cost reporting period that corresponds to the discharges for which the outlier payments are made. This adjustment would be made irrespective of whether the nationwide percentage of outlier payments relative to total operating DRG payments is equal to the outlier offset that is applied to the average standardized amounts (generally, 5.1 percent).

Outlier payments are intended to recognize the fact that hospitals occasionally face cases that are extraordinarily costly and otherwise not adequately compensated under an average-based payment system. However, we can only estimate actual costs based on the charges for a case because charges are the only data available that indicate the resource usage for an individual case. Therefore, our ability to identify true outlier cases is dependent on the accuracy of the cost-to-charge ratios. To the extent some hospitals may be motivated to maximize outlier payments by taking advantage of the lag in updating the cost-to-charge ratios, the payment system remains vulnerable to overpayments to individual hospitals. Therefore, we believe the only way to eliminate the potential for such overpayments is to provide a mechanism for final settlement of outlier payments using actual cost-to-charge ratios from final, settled cost reports.

However, the fixed-loss outlier threshold is an important aspect of the prospective nature of the IPPS. The outlier payment policy is designed to alleviate any financial disincentive hospitals may have against providing any medically necessary care their patients may require, even those patients who become very sick and require extraordinary resources. The preestablished threshold allows hospitals to approximate their Medicare payment for an individual patient while that patient is still in the hospital. Because we are proposing to base outlier payments on the hospital’s actual cost-to-charge ratios during the contemporaneous cost reporting period, the hospital should still be in a position to make this approximation. Hospitals have immediate access to the information needed to determine what their cost-to-charge ratio will be when their cost report is settled. Even if the final cost-to-charge ratio is likely to be different from the ratio used initially to process and pay the claim, as noted above, hospitals not only have the information available to estimate their cost-to-charge ratio, but also have the ability to control it, through the structure and levels of their charges.

If we were to make retroactive adjustments to outlier payments to ensure total payments are 5.1 percent of DRG payments (by retroactively adjusting outlier payments), we would be removing this important aspect of the prospective nature of the IPPS. Because such an across-the-board adjustment would either lead to more or less outlier payments for all hospitals, hospitals would no longer be able to reliably approximate their payment for a patient, while the patient is still hospitalized. We believe it would be neither necessary nor appropriate to make such an aggregate retroactive adjustment.

Furthermore, we do not believe it would be consistent with the intent of the language at section 1886(d)(5)(A)(iv) of the Act to do so. This section calls for the Secretary to ensure that outlier payments are equal to or greater than 5 percent and less than or equal to 6 percent of projected or estimated (not actual) DRG payments. We believe this language reflects Congress’s intent regarding the prospectivity of the IPPS. However, we believe it would prevent settling outlier payments based on hospitals’ actual cost-to-charge ratios during the period when the discharge occurs.

D. Fixed-loss Outlier Threshold

As noted above, under section 1886(d)(5)(A)(iv) of the Act, outlier payments for any year must be projected to be not less than 5 percent nor more than 6 percent of total estimated operating DRG payments plus outlier payments; and section 1886(d)(3)(B) of the Act requires the Secretary to reduce the average standardized amounts by a factor to account for the estimated proportion of total DRG payments made to outlier cases. Similarly, section 1886(d)(9)(B)(iv) of the Act requires the Secretary to reduce the average standardized amounts applicable to hospitals in Puerto Rico to account for the estimated proportion of total DRG payments made to outlier cases.

In the August 1, 2002 final rule, we established the FY 2003 outlier fixed-loss threshold at $33,560 (67 FR 50122). This was a nearly 60 percent increase over the FY 2002 threshold of $21,025. The primary reason for this dramatic increase was a change in our methodology to use the rate of increase in charges rather than the rate of increase in costs to determine the threshold. That is, because we use FY 2001 cases to project the threshold for FY 2003, it is necessary to inflate the charges on the FY 2001 bills to approximate the charges on a similar claim for FY 2003. Prior to the calculation of the FY 2003 outlier threshold, we used the rate of cost increase from the most recent cost reports available to inflate actual charges on the prior year’s bills to estimate what the charges would be in the upcoming year.

Our analysis indicated hospitals’ charges were increasing at a much faster rate than costs. Therefore, in the August 1, 2002 final rule, we changed our methodology to inflate charges (67 FR 50122). Rather than using the observed rate of increase in costs from the cost reports, we inflated the FY 2001 charges by a 2-year average annual rate of change in actual charges per case from FY 1999 to FY 2000, and from FY 2000 to FY 2001, to estimate what the charges would be in FY 2003 for a similar claim. This proposed rule would make several changes to better target outlier payments to the most costly cases. As a result, if our present proposals are implemented as part of our final policy, outlier payments to the hospitals that have been most aggressively increasing their charges to maximize outlier payments would be dramatically reduced. However, we are concerned that unrestrained charge increases may continue to occur during FY 2003 prior to the implementation of these proposed changes as final, and possibly may result in outlier payments in excess of the 5.1 percent offset established by the August 1, 2002 final rule. For example, hospitals intending to maximize outlier payments during FY 2003 could continue to do so by increasing charges enough to outpace increases in the threshold. In fact, given the public attention on this behavior over the past
few months and the potential for other hospitals to begin to aggressively increase their charges, and consequently their outlier payments, it is possible this type of aggressive gaming of the outlier policy has become more widespread in recent months.

Because of the extreme uncertainty regarding the effects of aggressive hospital charging practices on FY 2003 outlier payments to date, we are proposing no change to the FY 2003 fixed-loss threshold at this time. The threshold would remain at $33,560. However, we note that data for the first quarter of FY 2003 inpatient claims will be available soon, and these data may allow us to evaluate the current threshold and whether outlier payments to date appear to be approximately 5.1 percent of the total DRG payments.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the Federal Register and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

As discussed below, we are soliciting comment on the recordkeeping requirements, as referenced in the proposed amendments to §412.84 discussed in this proposed rule. Under the proposed amendments to §412.84(h), a hospital may request that its fiscal intermediary use a different (higher or lower) cost-to-charge ratio based on substantial evidence presented by the hospital. The burden imposed by this section is the time it takes to write the request. We estimate that 120 hospitals would make this request per year and that it would take each one 8 hours for a total annual burden of 960 hours.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:


IV. Impact Analysis

A. Introduction

We have examined the impacts of this proposed rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 19, 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.

B. Executive Order 12866

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).

We have determined that this proposed rule is a major rule as defined in 5 U.S.C. 804(2). Therefore, we have prepared the quantitative analysis presented in section IV.G. of this preamble.

C. Regulatory Flexibility Analysis

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 based on their nonprofit status or by having revenues of $5 million to $25 million in any 1 year. For purposes of the RFA, all hospitals and other providers and suppliers are considered to be small entities. Individuals and States are not included in the definition of a small entity. As stated above, we are presenting a quantitative analysis at section IV.G. of this preamble.

D. Effects on Rural Hospitals

Section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis for any proposed rule (and subsequent final rule) that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the procedures of section 603 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital with fewer than 100 beds that is located outside of a Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA). Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21) designated hospitals in certain New England counties as belonging to the adjacent NECMA. Thus, for purposes of the IPPS, we classify these hospitals as urban hospitals.

It is clear that the changes being proposed in this proposed rule would affect both a substantial number of small rural hospitals as well as other classes of hospitals, and that the effects on some hospitals might be significant. Therefore, the discussion in section IV.G. of this preamble, in combination with the rest of this proposed rule, constitutes a combined regulatory impact analysis and regulatory flexibility analysis.

E. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) also requires that agencies assess anticipated costs and benefits before issuing any proposed rule (or a final rule, which has been preceded by a proposed rule) that may result in an expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This proposed rule would not result in any unfunded mandates for State, local, or tribal governments or the private sector, as defined by section 202.

F. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this proposed rule in light of Executive Order 13132 and have
G. Quantitative Analysis

As described above, the changes we are proposing would better target outlier payments to the most costly cases. First, by proposing to use the cost-to-charge ratio to adjust charges, we have identified 123 hospitals that appear to have been most aggressively gaming the existing outlier policy. This change in approach would be likely to lead to inequitable treatment of some hospitals. We considered eliminating the alternative would be to not make any changes to the current outlier policy. However, we believe that in light of the evidence that hospitals have been manipulating our current outlier policy, it is important to change the current policy to ensure these payments go to truly expensive cases. Therefore, we do not believe that retaining our current policy is a viable option.

We also considered establishing a policy that hospitals’ cost-to-charge ratios would be based on their rates of increase in charges as an alternative to reconciling outlier payments on the cost reports. However, we believe this approach would be extremely complex. In addition, this approach would require us to make assumptions about the relationship between costs and charges that may not apply in particular circumstances. Therefore, this alternative would be likely to lead to inequitable treatment of some hospitals.

We considered eliminating the application of statewide average cost-to-charge ratios altogether. However, it is necessary to have some ratio to assign to new hospitals that have not yet filed their first cost report. Also, we believe it remains appropriate to assign the statewide average cost-to-charge ratio in cases where a hospital’s cost-to-charge ratio exceeds 3 standard deviations from the geometric mean.

I. Executive Order 12866

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

V. Response to Comments

Because of the large number of items of correspondence we normally receive on Federal Register documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the preamble to this document. And, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Change of the Required 60-Day Comment Period to a 30-Day Comment Period

Section 1871 of the Social Security Act provides that the Secretary shall provide for notice of any proposed regulation in the Federal Register and a period of not less than 60 days for public comment before issuing a regulation in final form. However, this notice-and-comment procedure may be waived if the agency, for good cause, finds that the notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and the reasons for it into the notice issued.

We believe there is good cause to waive the 60-day comment period. In light of the importance of the outlier issue and the extensive changes being proposed, however, we believe it is also important to provide a public comment period on the proposed policies, not because it is required, but as a matter of good public policy. Accordingly, in order to balance these competing interests, we are voluntarily providing a 30-day period for the submission of public comments.

The Congress intended that outlier payments would be made only in situations where the cost of care is extraordinarily high in relation to the average cost of treating comparable conditions or illnesses. Under our existing outlier methodology, if hospitals’ charges are not sufficiently comparable in magnitude to their costs, the legislative purpose underlying the outlier regulations is thwarted. In addition, if these proposed changes are not implemented expeditiously, additional hospitals will likely begin to increase their charges to take advantage of the vulnerabilities of the current system, and those hospitals that already have engaged in this activity will continue to do so. This has the undesirable impact not only of further distorting the distribution of outlier payments, but it also has negative impacts on other insurers and the public. In the case of other insurers, Medicare’s payments often serve as a benchmark for establishing their payments to individual hospitals. To the extent Medicare continues to pay excessive outlier payments to some hospitals, this may have spillover effects to private insurance companies. In the case of the public, particularly those without health insurance, they face the prospect of being expected to pay these exorbitant hospital charges when they
become hospitalized at an institution that has engaged in these practices. Extending the duration of these payment inequities would be contrary to the public interest and could adversely affect the provision of services to Medicare beneficiaries.

We believe that providing a 30-day comment period for the proposed policies in this document allows hospitals and the general public sufficient opportunity to address any concerns or issues that they may have, and at the same time, allows CMS to address the issue of excessive outlier payments within the current fiscal year (FY 2003). Hospitals are already familiar with the existing outlier payment policies and should be able to readily assess the impact that the proposed changes may have on their programs and respond to the proposed changes in the outlier payment methodology.

List of Subjects in 42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

For the reasons stated in the preamble of this proposed rule, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR part 412 as follows:

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

1. The authority citation for part 412 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. Section 412.84 is amended by—

A. Revising paragraph (h).

B. Redesignating paragraphs (i), (j), and (k) as paragraphs (j), (k), and (l), respectively.

C. Adding a new paragraph (i).

D. In redesignated paragraph (k), removing the phrase “paragraph (k) of this section” and adding in its place “paragraph (l) of this section.”

E. In redesignated paragraph (l), removing the phrase “paragraph (j) of this section” and adding in its place “paragraph (k) of this section.”

F. Adding a new paragraph (m).

The revisions read as follows:

§412.84 Payment for extraordinarily high-cost cases (cost outliers).

(h) For discharges occurring before the effective date of the final rule, the operating and capital cost-to-charge ratios used to adjust covered charges are computed annually by the intermediary for each hospital based on the latest available settled cost report for that hospital and charge data for the same time period as that covered by the cost report. Statewide cost-to-charge ratios are used in those instances in which a hospital’s operating or capital cost-to-charge ratios fall outside reasonable parameters. CMS sets forth the reasonable parameters and the statewide cost-to-charge ratios in each year’s annual notice of prospective payment rates published under §412.8(b).

(i)(1) For discharges occurring on or after the effective date of the final rule, the operating and capital cost-to-charge ratios applied at the time a claim is processed are based on either the most recent settled or the most recent tentative settled cost report, whichever is from the latest cost reporting period (unless otherwise specified by CMS based on later available data). A hospital may also request that its fiscal intermediary use a different (higher or lower) cost-to-charge ratio based on substantial evidence presented by the hospital. Such a request must be approved by the CMS Regional Office. If a fiscal intermediary is unable to determine an accurate operating or capital cost-to-charge ratio for a hospital in one of the following circumstances, it may use a statewide average cost-to-charge ratio:

(i) New hospitals that have not yet submitted their first Medicare cost report. (For this purpose, a new hospital is defined as an entity that has not accepted assignment of an existing hospital’s provider agreement in accordance with §489.18 of this chapter.)

(ii) Hospitals whose operating or capital cost-to-charge ratio is in excess of three standard deviations above the corresponding national geometric mean. This mean is recalculated annually by CMS and published in the annual notice of prospective payment rates published under §412.8(b).

(iii) Other hospitals for whom the fiscal intermediary determines accurate data upon which to calculate either an operating or capital cost-to-charge ratio (or both) are not available.

(2) For discharges occurring on or after the effective date of the final rule, any reconciliation of outlier payments will be based on operating and capital cost-to-charge ratios calculated based on a ratio of costs to charges computed from the relevant cost report and charge data determined at the time the cost report coinciding with the discharge is settled.

(m) Effective for discharges occurring on or after the effective date of the final rule, at the time the cost report is settled, outlier payments may be adjusted to account for the time value of any underpayments or overpayments. Any adjustment will be based upon a widely available index to be established in advance by the Secretary, and will be applied from the midpoint of the cost reporting period to the date of reconciliation.

§412.116 [Amended]

3. In §412.116(e), the second sentence is removed.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance)


Thomas A. Scully,
Administrator, Centers for Medicare & Medicaid Services.


Tommy G. Thompson,
Secretary.

[FR Doc. 03–5121 Filed 2–28–03; 12:03 pm]

BILLING CODE 4120–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 54

[CC Docket No. 96–45; FCC 03J–1]

Federal-State Joint Board on Universal Service Seeks Comment on Certain of the Commission’s Rules Relating to High-Cost Universal Service Support and the ETC Designation Process

AGENCY: Federal Communications Commission.

ACTION: Solicitation of comments.

SUMMARY: On November 8, 2002, the Federal Communications Commission requested that the Federal-State Joint Board on Universal Service “review certain of the Commission’s rules relating to the high-cost universal service support mechanisms to ensure that the dual goals of preserving universal service and fostering competition continue to be fulfilled.” In particular, the Commission asked the Joint Board to review the Commission’s rules relating to high-cost universal service support in study areas in which a competitive eligible telecommunications carrier is providing services, as well as the Commission’s rules regarding support for second lines. The Commission also asked the Joint Board to examine the process for designating ETCs. In this document, the Joint Board invite public comment on whether these rules continue to fulfill their intended purposes, whether