

1853(c)(7) of the Act. When the costs of NCDs and statutory coverage changes in a given year are determined to be "significant" under the new definition described above, these costs will be included in an "NCD adjustment factor" that will be added to the county rates in counties that will receive a 2 percent update. In other words, the 2 percent update will be applied to the newly adjusted rates. (The assumption is that the floor and blended rates are appropriately adjusted for new benefits because they are increased by the M+C growth rate that includes NCD and legislative changes in benefits estimates.) The "NCD adjustment factor" will be applied prospectively to the rate calculation for the year following the year after the NCDs and legislative benefit changes are effective. For example, NCDs and legislative changes determined to be significant in 2003 will be aggregated, and the "NCD adjustment factor" computed will be used to adjust payments for 2005. We have modified § 422.256(b) to codify in regulation this additional NCD adjustment factor adjustment to the M+C capitation rates.

*Comment:* One commenter supported the proposed rule and also asked whether the term "significant" would be defined as currently provided for in M+C regulations with a defined cost threshold.

*Response:* As discussed above, the proposed language at § 422.109(a) defining "significant cost" as it relates to the decision whether to make fee-for-service payment pursuant to section 1852(a)(5) of the Act is being retained.

As discussed above we are revising § 422.109 to provide that this definition will be applied to NCDs and legislative changes in benefits in the aggregate for purposes of the adjustments under § 422.256

#### 4. Restriction on Implementation of Significant New Regulatory Requirements Midyear

Section 612 of the BIPA amended section 1856(b) of the Act to prohibit us from imposing significant new regulatory requirements on an M+C organization or plan, other than at the beginning of a calendar year. Comments on this issue and our responses follow.

*Comment:* One commenter asked that we use the term "requirements" instead of "regulations" in § 422.521. The commenter's reasoning for suggesting the use of "requirements" was that most documents from our agency that impose significant new cost or burdens are not in the form of regulations but are in the form of memoranda, guidance, manual chapters and the like.

*Response:* We agree with the commenter that requirements are often imposed through vehicles other than regulations. Therefore, in response to this comment, we are revising § 422.521 to extend the prohibition in section 612 of the BIPA to all requirements, not just those imposed in regulations. We note that we had previously made this commitment administratively.

*Comment:* One commenter requested that we define significant cost or burden as it is used in § 422.521. The commenter also suggested that we base the definition on cost or operational assessments conducted by us and by M+C organizations.

*Response:* We generally agree with the commenter and will explore methods to better define the meaning of "cost and burden" as those terms are used in § 422.521. However, we are leaving the text of § 422.521 unchanged.

#### 5. Election of Uniform Local Coverage Policy for a Medicare+Choice Plan Covering Multiple Localities

Section 615 of the BIPA amended section 1852(a)(2) of the Act by adding a section that allows M+C organizations to achieve greater consistency of benefits for M+C plans covering multiple localities. In providing Medicare covered benefits to its enrollees, each M+C organization ordinarily must comply with, among other things, written coverage decisions of local carriers and intermediaries with jurisdiction for claims in the geographic area in which the services are covered under the M+C plan. Some M+C organizations have plans that cover a large area, either a State or multiple counties in a State. Section 615 of the BIPA allows M+C organizations that offer a plan in a geographic area to which more than one local coverage policy applies, to uniformly apply the local coverage policy that is most advantageous to M+C enrollees in the plan. We will make the final determination as to which local coverage policy is most beneficial to M+C enrollees.

By electing to use this uniform coverage policy, M+C organizations can benefit from economies of scale when printing and distributing marketing materials and descriptions of benefits for their M+C plans. This policy will also enable M+C organizations to standardize coverage decisions and provider contracts across entire plans, rather than having different policies apply in different geographic areas of the same plan. We received three comments on our proposed revision.

*Comment:* Two commenters suggested that we apply the newly allowed

uniform coverage policy rule across all M+C plans offered by an M+C organization and/or its subsidiaries. One commenter argued that such an expansion of the rule would serve both consistency and uniformity, as well as provide for significant cost-savings for multi-state M+C organizations.

*Response:* Section 615 of the BIPA is clear in restricting our authority to permit an M+C organization's election of a uniform local coverage policy to a specific plan offered by an M+C organization. The statute does not permit application of the uniform local coverage policy across different plans offered by a single M+C organization and/or its subsidiaries.

*Comment:* One commenter requested further guidance on the criteria that we will use to determine the local coverage policy that is most beneficial to M+C enrollees in a plan whose service area encompasses more than one local coverage policy area. The commenter also suggested allowing the M+C organization to identify the local coverage policy that it believes would be most beneficial to its enrollees. The M+C organization would notify us, providing justification for the local medical review policy selected as the most beneficial to its enrollees. If we did not disagree within 60 days of receipt of notice, the M+C organization's proposal would be deemed approved.

*Response:* We agree that clarification is needed for both the criteria that we will use in evaluating the local coverage policies that are most beneficial to M+C enrollees and the time frame within which that evaluation will occur. Since the benefits covered by a plan are essential to preparation of the adjusted community rate (ACR) proposal related to that plan (see § 422.306), an M+C organization proposing to adopt a uniform coverage policy for a plan must notify us 60 days prior to the date the ACR proposal for that plan is due. We believe that a 60-day window will permit us sufficient time to fully evaluate the proposed uniform coverage policy election related to a plan, and to notify the M+C organization of our decision, while still allowing sufficient time for the M+C organization to prepare and submit its ACR proposal in a timely manner. Therefore, we have added a new section § 422.101(b)(3)(i) which explains the time frame within which an M+C organization must notify us of its intent to adopt a uniform local coverage policy for a plan. In addition, we have added § 422.101(b)(3)(ii) which establishes the factors we will consider to evaluate the local coverage policy that is most beneficial to M+C enrollees. We, in turn, will notify the M+C