reported with HCPCS codes C5271 through C5278 and the applicable skin substitute HCPCS Q-code. In addition, the few skin substitute products that are applied as either liquids or powders per milliliter or per milligram and are currently employed in procedures outside of the CPT code range of 15271 through 15278 will not be classified as either high cost or low cost, but will be packaged into the surgical procedure in which they are used.

The skin substitute products that are unconditionally packaged under this final policy and assigned to status indicator ''N'' for CY 2014 are listed in Addendum P to this CY 2014 OPPS/ASC final rule with comment period. The payment for CPT codes 15271 through 15278 for surgical application of high cost skin substitutes (payment rate per square centimeter over $32 for CY 2014) and HCPCS codes C5271 through C5278 for surgical application of low cost skin substitutes (payment rate per square centimeter $32 and under for CY 2014), including the cost of the packaged skin substitutes, for CY 2014, are listed in Addendum B to this final rule with comment period. The OPPS addenda are available on the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

(3) Clinical Diagnostic Laboratory Tests

Since the beginning of the OPPS, clinical diagnostic laboratory tests (laboratory tests) provided in the hospital outpatient setting have been separately paid to hospitals at Clinical Laboratory Fee Schedule (CLFS) rates (65 FR 18442). Section 1833(t)(1)(B)(i) of the Act authorizes the Secretary to designate the hospital outpatient services that are paid under the OPPS. Under this authority, the Secretary excluded from the OPPS those services that are paid under fee schedules or other payment systems. As stated in the April 17, 2000 OPPS final rule with comment period: ''Rather than duplicate existing payment systems that are effectively achieving consistency of payments across different service delivery sites, we proposed to exclude from the outpatient PPS those services furnished in a hospital outpatient setting that were already subject to an existing fee schedule or other prospectively determined payment rate'' (65 FR 18442). Because payment rates for laboratory tests were based on the CLFS, laboratory tests are among the services excluded from the OPPS. We codified this policy at 42 CFR 419.22(l).

As discussed above, it is our intent to revise the structure of the OPPS to adopt greater aspects of a prospective payment system and retain less of a fee schedule structure, which makes separate payment for each separately coded item. We have examined the services performed in the hospital outpatient setting to determine those services that we believe should be packaged in order to make the OPPS a more complete and robust prospective payment system. We were guided by our longstanding OPPS packaging principle of packaging the payment of items or services when they are provided along with primary services they support. Based on this approach, we believe that laboratory tests (other than molecular pathology tests, as discussed below) that are integral, ancillary, supportive, dependent, or adjunctive to the primary services provided in the hospital outpatient setting are services that should be packaged. Laboratory tests and their results support clinical decision making for a broad spectrum of primary services provided in the hospital outpatient setting, including surgery and diagnostic evaluations. Therefore, except as discussed below for molecular pathology tests, in the CY 2014 OPPS/ASC proposed rule (78 FR 43572), we proposed to package laboratory tests when they are integral, ancillary, supportive, dependent, or adjunctive to a primary service or services provided in the hospital outpatient setting. Specifically, we proposed that laboratory tests would be integral, ancillary, supportive, dependent, or adjunctive to a primary service or services provided in the hospital outpatient setting and appropriate for packaging into the payment of the primary service when they are provided on the same date of service as the primary service and when they are ordered by the same practitioner who ordered the primary service. We stated that the laboratory test codes that we were proposing to be packaged and assigned status indicator ''N'' for CY 2014 were listed in Addendum P to the proposed rule (which is available via the Internet on the CMS Web site). We also proposed to revise the regulation text at § 419.2(b) and § 419.22(l) to reflect this laboratory test packaging proposal.

We stated that we would consider a laboratory test to be unrelated to a primary service and, therefore, not part of the proposed packaging policy when the laboratory test is the only service provided on a date of service or when the laboratory test is provided on the same date of service as the primary service but is ordered for a different purpose than the primary service by a practitioner different than the practitioner who ordered the primary service provided in the hospital outpatient setting. We stated that laboratory tests not included in the packaging proposal would continue to be paid separately at CLFS rates when billed on a 14X bill type. We note that hospitals already use the 14X bill type to bill for referred specimens or any situation where the beneficiary receives laboratory tests but is not a registered outpatient of the hospital.

We also proposed an exception to our proposal to package laboratory tests for molecular pathology tests described by CPT codes in the ranges of 81200 through 81383, 81400 through 81408, and 81479. We did not propose that these services be packaged because we believe that these relatively new tests may have a different pattern of clinical use, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that we proposed to package. As we gain more experience with molecular pathology tests, we stated that we will consider if packaging them in the OPPS in the future would be appropriate. These services would continue to be billed on a 13x claim and be assigned status indicator ''A.''

In addition to the laboratory packaging policy proposals described above, we considered proposing an alternative laboratory packaging policy that would package those laboratory tests meeting the proposed policies above, but exclude laboratory tests with costs greater than some dollar threshold similar to the approach we use for separately paid drugs and biologicals in the OPPS so that only laboratory tests (meeting the proposed standards above) with CLFS payment rates below a certain dollar threshold amount would be packaged. Under this alternative policy, tests meeting the proposed standards above, but for which the CLFS payment rates are above the threshold amount, would continue to be separately paid. We decided not to propose this alternative policy because, as discussed above in the background section, our packaging policies generally do not consider the cost of the individual items and services that are packaged, meaning that we package both inexpensive and expensive items according to OPPS packaging principles.

We recognize that the Medicare Part B deductible and coinsurance generally do not apply for laboratory tests paid to hospitals at CLFS rates and that the deductible and coinsurance would apply to laboratory tests packaged into other services in the OPPS. The purpose

of the laboratory packaging proposal was not to shift program costs onto beneficiaries. It is to encourage greater efficiency by hospitals and the most economical delivery of medically necessary laboratory tests which would contain unnecessary growth in hospital outpatient spending over the long run, which benefits all stakeholders. We stated that we estimate that the combination of packaging laboratory tests into a wide array of primary services provided in the hospital outpatient setting combined with our longstanding methodology to adjust the copayment percentages to 20 percent as provided in section 1833(t)(3)(B)(ii) of the Act and as discussed in section II.I. of the proposed rule (78 FR 43586 through 43587), and the limitation on the copayment amount for a procedure to the inpatient hospital deductible as set forth at section 1833(t)(8)(C)(i) of the Act would fully offset the financial impact on Medicare beneficiaries receiving laboratory tests that would be subject to the proposed packaging policy.

Further, we stated that we believe that creating these larger bundles will result in a more efficient use of laboratory tests when they are adjunctive to an outpatient service. In addition, to the extent that the coinsurance and deductible do not apply under the CLFS, they would continue not to apply for tests that are ordered, provided, and billed independently from a primary service as discussed above, or for molecular pathology tests. We invited public comments on the effect of packaging laboratory tests on beneficiary coinsurance.

Comment: Some commenters supported the proposal to package laboratory tests because they believed that packaging laboratory tests is consistent with CMS' goal to move the structure of the OPPS closer to a prospective payment system and away from a fee schedule construction.

Response: We appreciate the commenters' support.

Comment: A few commenters opposed the proposal to package laboratory tests because they believed that it could harm beneficiary access to these laboratory tests.

Response: We disagree. We believe that beneficiaries will continue to receive laboratory tests that are medically necessary. We are continuing to pay for these laboratory tests and have included the cost of the associated laboratory tests with the estimated cost of primary hospital outpatient services when establishing payment for these services. We believe that packaged payment will allow hospitals to better assess when and which laboratory tests are appropriate and provide these services more efficiently, but that this policy will not affect beneficiaries' access to reasonable and appropriate care.

Comment: A few commenters opposed the proposal to package laboratory tests because they believed that it would not achieve CMS' objective of greater cost efficiency in hospitals.

Response: We disagree. Packaging encourages efficiency and is an essential component of a prospective payment system. Packaging payment for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service has been a fundamental part of the OPPS since its implementation in August 2000. We believe that packaging encourages hospitals to furnish services in the most efficient way by enabling hospitals to manage their resources with the maximum flexibility, thereby encouraging long-term cost containment. Therefore, our packaging policies support our strategic goal of incentivizing hospitals to provide appropriate care in the most efficient manner.

Comment: One commenter suggested that CMS does not have the legislative authority to package laboratory tests in the OPPS. The commenter states that section 1833(h)(1)(A) of the Act requires that CMS pay for laboratory tests (except inpatient laboratory tests) in all settings according to the CLFS.

Response: We disagree. Although section 1833(h)(1)(A) of the Act established the CLFS, it does not prohibit outpatient laboratory tests from being paid either separately or as part of a packaged payment under the OPPS. Section 1833(t) of the Act gives the Secretary discretion to designate which services are covered OPD services, with the exception of those listed in section 1833(t)(1)(B)(iv) of the Act, and laboratory tests are not among the services listed in section 1833(t)(1)(B)(iv) of the Act. Laboratory tests provided in the hospital outpatient department have always been considered hospital outpatient services. However, until this proposal, we have since the inception of the OPPS elected to separately pay for laboratory tests in the hospital outpatient setting at the CLFS payment rates. For CY 2014, we proposed to include certain laboratory tests as covered OPD services under the OPPS, and we proposed to package payment for certain tests, similar to other covered outpatient services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary hospital outpatient services under the OPPS.

Comment: A few commenters expressed concern about increased beneficiary liability associated with laboratory tests being paid under the OPPS, which has a coinsurance obligation, unlike payment for laboratory tests under the CLFS, which does not have an associated coinsurance obligation by statute. One commenter also requested that, if CMS does finalize the laboratory test packaging policy for CY 2014, it exclude laboratory tests from the services into which they are packaged for the purpose of determining the coinsurance amount.

Response: We appreciate the commenters' concern about the welfare of Medicare beneficiaries. We assessed the financial impact of packaging laboratory tests on beneficiaries for the proposed rule and reassessed the impact for this final rule with comment period. We estimated in the proposed rule that the combination of packaging laboratory tests into a wide array of primary services provided in the hospital outpatient setting combined with our longstanding methodology to adjust the copayment percentages to 20 percent, as provided in section 1833(t)(3)(B)(ii) of the Act and as discussed in section II.I. of the proposed rule (78 FR 43573, 43586 through 43587), and the limitation on the copayment amount for a procedure to the inpatient hospital deductible as set forth at section 1833(t)(8)(C)(i) of the Act, would offset the financial impact on Medicare beneficiaries receiving laboratory tests that will be subject to the finalized packaging policy.

In this final rule with comment period, we are not finalizing our proposed policy to package ancillary services with a CY 2013 status indicator of ''X'' and diagnostic tests on the bypass list in response to public comments. We estimate that, in aggregate, the percentage of beneficiary liability for OPPS payments for CY 2014, including payment for certain clinical diagnostic laboratory tests, will be 21.7 percent in CY 2014, consistent with aggregate beneficiary liability under the OPPS in recent years. We believe that our final policy to create 29 comprehensive APCs for CY 2015 will reduce the aggregate beneficiary liability in CY 2015.

In addition, we believe that creating larger payment bundles will result in a more efficient use of clinical diagnostic laboratory tests when they are integral or supportive of an outpatient service. Furthermore, to the extent that the coinsurance and deductible do not apply under the CLFS, they would

continue not to apply for tests that are ordered, provided, and billed independently from a primary service as discussed above, or for molecular pathology tests, which will continue to be paid under the CLFS.

Regarding the commenter's request that CMS exclude laboratory tests from the services into which they are packaged for the purpose of determining the coinsurance amount, we do not have the authority under section 1833(t)(8) of the Act to exclude laboratory tests from the services into which they are packaged for the purpose of determining the coinsurance amount.

Comment: Some commenters expressed concern about CMS' proposed exception to packaging for laboratory tests provided on the same date of service as another hospital outpatient service or services, but that are ordered by a different practitioner than the practitioner who ordered the primary hospital outpatient service or services and where the ordered laboratory test also is for a different purpose than the primary service. Commenters were concerned about hospitals' administrative burden associated with billing for separately paid laboratory tests. Commenters suggested that CMS implement claims processing changes and instructions in advance of adopting the laboratory packaging policy to ease hospitals' transition to this policy and the exceptions to this policy.

Response: We believe that these commenters may have misunderstood the nature of the proposed laboratory packaging policy. We proposed to package laboratory tests when they are integral, ancillary, supportive, dependent, or adjunctive to a primary service or services provided in the hospital outpatient setting; that is, when they are provided on the same date of service as the primary service and when they are ordered by the same practitioner who ordered the primary service. One exception to our proposal to package laboratory tests is to exempt molecular pathology tests, which would continue to be separately paid when billed on a 13x claim.

A laboratory test can be separately paid when (1) the laboratory test is the only service provided to that beneficiary on that date of service; or (2) the laboratory test is on the same date of service as the primary service but is ordered for a different purpose than the primary service by a practitioner different than the practitioner who ordered the primary service. When a laboratory test is the only service provided to a beneficiary at the hospital, the hospital can receive separate payment for those laboratory tests by billing for these services on a 14x claim; we would pay hospitals for these laboratory tests based on the CLFS payment rate. To illustrate the second scenario, a beneficiary has eye surgery scheduled with physician A, an ophthalmologist, but also has an order from physician B, a cardiologist, for unrelated laboratory tests. The beneficiary goes to the hospital for the eye procedure and decides to have the laboratory tests that have been ordered by physician B for a different purpose than the eye procedure on the same date of service. While the laboratory test is on the same date of service as the eye procedure, the laboratory tests are ordered for a different purpose than the primary service by a practitioner different than the practitioner who ordered the eye procedure. In this situation, the hospital can bill Medicare for the unrelated laboratory tests on a 14x claim and receive separate payment under the CLFS, similar to when the laboratory tests are the only service performed in the hospital outpatient department on a given date of service. However, if, in this example, physician A also ordered some laboratory tests as a part of a preoperative evaluation for the eye procedure and the beneficiary had the tests on the same date of service as the eye procedure, then the hospital would report those laboratory tests on a 13x claim along with the eye surgery. Payment for those preoperative laboratory tests would be packaged into the payment for the surgery, which is the primary procedure that would be paid separately. It will be the hospital's responsibility to determine when to separately bill laboratory tests on the 14x claim according to this description of these limited exceptions. We plan to issue revised contractor instructions for billing for these laboratory tests on a 14x bill type in January 2014, and we also will install claims processing edits.

Comment: A few commenters suggested that CMS adopt the alternative laboratory packaging policy discussed briefly above and in the proposed rule (78 FR 43573) to package only those laboratory tests with payment rates below some dollar threshold, similar to the approach that CMS uses for most drugs, biologicals, and therapeutic radiopharmaceuticals in the OPPS. Commenters stated that such a policy would enable hospital specialty clinics to perform more complex, expensive, and esoteric laboratory tests.

Response: We appreciate the commenters' thoughts on this alternative. We continue to believe that a dollar packaging threshold is not appropriate for laboratory tests because almost all laboratory tests are inexpensive (97 percent of all laboratory tests have CLFS national limitation amounts of less than $100) relative to other services that are provided in the hospital outpatient department. This is unlike many of the drugs and biologicals that are used in the hospital outpatient department that not uncommonly cost thousands of dollars per dose. Therefore, we continue to believe that it is not necessary to adopt a payment threshold policy for packaging laboratory tests similar to the threshold policy for packaging drugs and biologicals.

Comment: A few commenters requested additional exceptions to the proposal to package specific laboratory tests, including, for example, tests for in situ hybridization and cardiovascular screening. These commenters stated that, like molecular pathology tests for which CMS proposed an exception to the proposal to conditionally package laboratory tests, these tests have a different pattern of clinical use than most other laboratory tests and, therefore, should continue to be separately paid in the hospital outpatient setting.

Response: After considering the various requests for exceptions for specific laboratory tests that we received, we do not believe that additional exceptions to the laboratory packaging policy are necessary. We understand that there are laboratory tests that are less common and frequent than a standard panel, such as new tests. We do not believe that the tests described by the commenters or other laboratory tests that were proposed to be packaged are similar to the tests in the molecular pathology test series such that additional exceptions are warranted. We proposed to exclude the molecular pathology tests from our packaging proposal because, as a class of laboratory tests, their overall pattern of clinical use has not yet developed and we believe that these tests are less tied to a primary service than other laboratory tests. Once their pattern of use develops, we will assess whether we believe these laboratory tests also should be conditionally packaged. We do not believe that in situ hybridization and cardiovascular screening or other types of laboratory tests are a developing class of laboratory tests for which we do not know the pattern of use. For example, in situ hybridization may be a part of a comprehensive evaluation for a suspected malignancy. In response to commenter requests for additional exceptions, we also reviewed all of the laboratory tests listed in Addendum P to the proposed rule and do not believe that further exceptions to

our proposal to conditionally package laboratory tests are necessary.

After consideration of the public comments we received, for CY 2014, we are finalizing our proposal without modification to package laboratory tests in the OPPS when they are integral, ancillary, supportive, dependent, or adjunctive to a primary service or services provided in the hospital outpatient setting; that is, when they are provided on the same date of service as the primary service and when they are ordered by the same practitioner who ordered the primary service. This means that a laboratory test will not be packaged when (1) a laboratory test is the only service provided to that beneficiary on that date of service; or (2) a laboratory test is conducted on the same date of service as the primary service but is ordered for a different purpose than the primary service by a practitioner different than the practitioner who ordered the primary service. We also are finalizing our proposal without modification to except molecular pathology tests described by CPT codes in the ranges of 81200 through 81383, 81400 through 81408, and 81479 from this packaging proposal. In addition, we are finalizing our proposal without modification to revise the regulation text at § 419.2(b) and § 419.22(l) to reflect this conditional laboratory test packaging policy.

The laboratory test codes subject to this packaging policy will be assigned status indicator ''N'' because any laboratory tests reported on a 13x bill type will be packaged for CY 2014. These codes are listed in Addendum P to this final rule with comment period (which is available via the Internet on the CMS Web site).

(4) Procedures Described by Add-On Codes

Add-on codes describe procedures that are always performed in addition to a primary procedure. CPT defines add-on codes as codes that describe ''procedures [that] are commonly carried out in addition to the primary procedure performed,'' and also states that ''[a]dd-on codes are always performed in addition to the primary service or procedure and must never be reported as a stand-alone code'' (2013 CPT Codebook Professional Edition, page xi). CPT add-on codes are listed in Appendix D of the CPT codebook. Add-on codes can also be Level II HCPCS codes. For example, the procedure described by CPT code 11001 is ''Debridement of extensive eczematous or infected skin; each additional 10% of the body surface, or part thereof (list separately in addition to code for primary procedure).'' This code is used for additional debridement beyond that described by the primary procedure code. Historically, the OPPS has generally paid separately for add-on codes based on an APC assignment with status indicator ''T'' indicating that the multiple procedure payment reduction for surgeries applies.

Procedures described by add-on codes represent an extension or continuation of a primary procedure, which means that they are typically supportive, dependent, or adjunctive to a primary service, which is usually a surgical procedure. The primary code defines the purpose and typical scope of the patient encounter and the add-on code describes incremental work, when the extent of the procedure encompasses a range rather than a single defined endpoint applicable to all patients. The CPT codebook states that an add-on code describes ''additional intra-service work associated with the primary procedure'' (2013 CPT Codebook Professional Edition, page xi). For example, add-on CPT code 11001 is used for each additional 10 percent of debridement beyond that described by the primary code. Given the dependent nature and adjunctive characteristics of procedures described by add-on codes and in light of longstanding OPPS packaging principles described above, we believe add-on procedures should be packaged with the primary procedure. In the CY 2014 OPPS/ASC proposed rule (78 FR 43573), we proposed to unconditionally package all procedures described by add-on codes in the OPPS.

Aside from advancing the OPPS as a prospective payment system by packaging add-on codes, an additional benefit to packaging add-on codes is more accurate OPPS payment for procedures described by add-on codes. Currently, calculating geometric mean costs for procedures described by add-on codes is problematic in the OPPS because, as with many claims with multiple procedures, we cannot determine which costs on a claim are attributable to the primary procedure and which costs are attributable to the add-on procedure. Furthermore, because we use single claims and pseudo single procedure claims for ratesetting, we generally must rely on incorrectly coded claims containing only the add-on code to determine payment rates for add-on procedures. Claims containing only an add-on code are incorrectly coded because they should be reported with (or ''added-on'' to) a primary procedure. Packaging the line item costs associated with an add-on code into the cost of the primary procedure will help address this ratesetting problem because the costs of the add-on code would be packaged into the primary procedure, and we would no longer have to use miscoded claims to calculate estimated costs for add-on codes. Packaging add-on codes also would increase the number of single bills available for ratesetting for the primary procedures. We discuss how we model claims to establish relative payment weights, including definitions of multiple, single, and pseudo single claims in section II.A.2. of this final rule with comment period.

We proposed to revise the regulations at § 419.2(b) to include the packaging of add-on codes. The specific add-on codes that we proposed to be unconditionally packaged and assigned status indicator ''N'' for CY 2014 are listed in Addendum P to the proposed rule, which is available via the Internet on the CMS Web site.

Comment: Some commenters supported the proposal to package add-on codes, and agreed with CMS that packaging add-on codes is consistent with a prospective payment system and will improve OPPS ratesetting.

Response: We appreciate the commenters' support.

Comment: Several commenters objected to the proposal to package add-on codes for the following reasons:

- According to the commenters, procedures described by add-on codes are not necessarily integral, ancillary, supportive, dependent, or adjunctive to the primary service into which they would be packaged.
- Some procedures described by add-on codes include expensive implantable medical devices, and although they are integral to the primary procedure, commenters note that packaging these procedures into the primary procedure risks significant underpayment for the overall procedure that includes additional medical devices, which could negatively affect patient access to these devices.
- Add-on code packaging should not apply to infrequently performed add-on codes as the cost of these infrequent services will not be sufficiently reflected in the payment for the primary procedure.
- Some add-on codes are not related to the primary procedure but represent incremental additional physician work, and for this reason should not be packaged.

To insure continued patient access to these procedures, commenters requested that CMS establish exceptions to its proposal to package add-on codes for specific services that commenters believed would be underpaid under the policy, including, but not limited to,