

than 2 years nor any longer than 3 years. The drugs and biologicals that are due to expire on December 31, 2003 meet that criterion. Table 11 lists the drugs and biologicals for which pass-through status will expire on December 31, 2003.

TABLE 11.—LIST OF DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH STATUS EXPIRES CY 2004

HCPDS	APC	Long descriptor	Trade name	Pass-through expiration date
C9202	9202	Injection, suspension of microspheres of human serum albumin with octafluoropropane, per 3ml.	Optison (single source)	12-31-03
J0587	9018	Injection, Botulinum toxin, type B, per 100 units	Myobloc (single source)	12-31-03
J0637	9019	Injection, Caspofungin acetate, 5 mg	Cancidas (single source)	12-31-03
J7517	9015	Mycophenolate mofetil, oral per 250 mg	CellCept (single source)	12-31-03
J9010	9110	Injection, Alemtuzumab, per 10 mg	Campath (single source)	12-31-03
J9017	9012	Injection, Arsenic trioxide, per 1 mg	Trisenox (single source)	12-31-03
J9219	7051	Implant, Leuprolide acetate, per 65 mg implant	Viadur (single source)	12-31-03

Comment: A commenter requested that we maintain transitional pass-through status for this biological through calendar year 2004. The commenter indicated that Dermagraft was approved as a pass-through device effective October 1, 2000 through March 31, 2001, by which time CMS had concluded that Dermagraft should be classified as a biological for payment purposes. Dermagraft later re-qualified for pass-through status as a biological effective April 1, 2002. The commenter stated that CMS should not count the time Dermagraft was on the pass-through list as a device to determine whether this product received a minimum of 2 years under pass-through status.

Response: We agree with the commenter and will retain Dermagraft in pass-through status through December 2004.

Comment: The manufacturer of an ultrasound contrast agent, Optison (APC 9202, C9202), expressed concern about our decision to retire their product from pass-through status on December 31, 2003. The manufacturer indicated that two of Optison's competitors, Definity (C9112) and Imagent (C9203) will remain pass-throughs in 2004 and receive higher payments, while payment for Optison will be based on median cost calculated from hospital claims data. The commenter was concerned about differential OPPS payments to hospitals for clinically similar products and recommended that we should either allow all of these agents to remain on pass-through status until December 31, 2004, or remove them and use claims data to establish a uniform payment rate for 2004.

Response: As stated above, section 1833(t)(6)(C)(i) of the Act specifies that transitional pass-through payments for drugs and biologicals must be made for at least for 2 years but not more than 3 years. Pass-through payment for Optison was established on April 1, 2001, while Definity and Imagent received pass-

through status on April 1, 2002 and April 1, 2003, respectively. Since hospitals have been billing for and receiving pass-through payments for Optison for at least 2 years, we have the statutory authority to remove this item from pass-through status. Since pass-through payments for Definity and Imagent have not exceeded the minimum 2-year period yet, these products will retain their special status in 2004. In the absence of verifiable external data, the 2004 payment rate for Optison was calculated using hospital claims data from April through December 2002 and was eligible for dampening.

2. Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

To the maximum extent possible, our intention is to package into the APC payment the costs of any items and supplies that are furnished with an outpatient procedure. For 2004, we proposed to continue with our policy of paying separately for drugs and radiopharmaceuticals whose median cost per day exceeds \$150 and packaging the cost of drugs and radiopharmaceuticals with median cost per day of less than \$150 into the procedures with which they are billed. In the proposed rule, we set forth the methodology we used to calculate the median cost per day for drugs, biologicals, and radiopharmaceuticals (68 FR 47996-47997).

We proposed to provide an exception in 2004 to the packaging rule for drugs and radiopharmaceuticals whose payment status would change as a result of using newer data. For 2004, we proposed that:

- Currently packaged drugs and radiopharmaceuticals with median costs per day at or above \$150 would receive separate payment in 2004.
- Currently separately payable drugs and radiopharmaceuticals with median costs per day under \$150 would

continue to receive separate payment in CY 2004.

- Drugs whose pass-through status would expire on December 31, 2003, and whose median costs per day are under \$150 would receive separate payment in 2004.

- Currently packaged drugs and radiopharmaceuticals with median costs per day below \$150 would remain packaged in 2004.

We requested comments on the methodology we used to determine the median cost per day, on the threshold we proposed to use for packaging drugs and radiopharmaceuticals, and on the proposal to pay separately for drugs and radiopharmaceuticals whose payment status would change based on use of recent claims data and our proposed methodology. We also requested comments on alternatives to packaging.

We received many comments on our proposals, which are summarized below along with our responses.

Comment: We received many comments from patient advocates, individual clinicians, physician and nursing professional associations, individual hospitals, and manufacturers and their representatives that expressed significant concerns over our proposal to continue the 2003 policy under which we package the cost of most drugs, biologicals and radiopharmaceuticals that cost \$150 or less. We also received several comments from major provider groups in support of the packaging proposal and recommending a higher threshold. One such organization recommends that we study this issue further to develop a more appropriate long-term solution.

Commenters who disagreed with the proposal to package drugs, biologicals and radiopharmaceuticals costing \$150 or less believe that the proposed rates for the drug administration codes do not adequately address the costs of hospitals to administer these drugs. Several commenters conducted their own analyses of this issue in conjunction