ARIZONA—CARBON MONOXIDE—Continued

Designated area	Designation		Classification	
	Date	Type	Date	Type
23. thence, easterly along the southern line of Township 1 South to a point where the south line of Township 1 South intersects with the western line of Range 1 East, which line is generally the southern boundary of Estrella Mountain Regional Park; 24. thence, southerly along the western line of Range 1 East to the southwest corner of Section 18, Township 2 South, Range 1 East, said line is the western boundary of the Gila River Indian Reservation; 25. thence, easterly along the southern boundary of the Gila River Indian Reservation which is the southern line of Sections 13, 14, 15, 16, 17, and 18, Township 2 South, Range 1 East, to the boundary between Maricopa and Pinal Counties as described in Arizona Revised Statutes Sections 11–109 and 11–113, which is the eastern line of Range 1 East; 26. thence, northerly along the eastern boundary of Range 1 East, which is the common boundary between Maricopa and Pinal Counties, to a point where the eastern line of Range 1 East intersects the Gila River; 27. thence, southerly up the Gila River to a point where the Gila River intersects with the southern line of Township 2 South; and 28. thence, easterly along the southern line of Township 2 South to the point of beginning which is a point where the southern line of Township 2 South intersects with the easter line Range 7 East; 29. except that portion of the area defined by paragraphs 1 through 28 above that lies within the Gila River Indian Reservation.				

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[FR Doc. 05–17539 Filed 9–2–05; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

CMS–1325–IFC2

RIN 0938–AN58

Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B: Interpretation and Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Interim final rule; interpretation and correction.

SUMMARY: This interim final rule clarifies our timeline for implementation of the competitive acquisition program under section 1847B of the Social Security Act and corrects technical errors that appeared in the addenda to the interim final rule with comment period published in the **Federal Register** on July 6, 2005 entitled ''Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B.''

EFFECTIVE DATE: This rule is effective September 6, 2005.

FOR FURTHER INFORMATION CONTACT: Lia Prela, (410) 786–0548.

SUPPLEMENTARY INFORMATION:

I. Background

A. Clarification of Timeline for Implementation of CAP

On July 6, 2005, we published an interim final rule with comment period (70 FR 39022) in the **Federal Register** with respect to provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) that require the implementation of a competitive acquisition program (CAP) for certain Medicare Part B drugs not paid on a cost or prospective payment system basis. Physicians will generally be given a choice between obtaining these drugs from vendors selected through a competitive bidding process or directly purchasing these drugs and being paid under the average sales price (ASP) system.

In the July 6, 2005 interim final rule, we stated that implementation of the CAP would take place on January 1, 2006 to coordinate the CAP physician election process with the Medicare participating physician election process described in section 1842(h) of Social Security Act (the Act). Subsequent to the publication of the July 6, 2005 interim final rule, we received comments requesting a delay in implementation of the CAP from a variety of sources including written public comments as well as comments voiced during the conference call for potential vendors that we held on July 8, 2005.

Effective August 3, 2005, we suspended the vendor bidding process that began with publication of the interim final rule on July 6, 2005, to allow us more time to fully review public comments on the interim final rule and also to further refine the bidding process. We provided notification of the suspension on the CMS Web site *http://www.cms.hhs.gov/providers/drugs/compbid/* and through the pharmacy and physician Listservs. We will publish a final rule for implementing the CAP after we analyze the additional comments on the interim final rule and determine the best manner for improving the efficiency of the CAP and increasing potential participation of both vendors and physicians in the program.

We will announce the dates for the new vendor bidding period concurrent with the publication of the final rule. We also will be announcing a special physician election period. Currently, we expect that drugs will first be delivered through the CAP by July 2006. During the special election period, physicians will have the opportunity to elect to participate in the CAP from its start date in 2006 through the end of calendar year 2006.

As we specified in the July 2005 **Federal Register** document, we will continue to accept comments on the interim final rule until September 6, 2005.

In section II of this document, we provide clarification of the timeline for implementation of the CAP as well as further interpretation of what will

constitute an ''exigent circumstance'' for purposes of allowing a physician to elect to participate in the CAP and select a CAP vendor at a time other than the annual election period.

B. Corrections to the July 6, 2005 Interim Final Rule

In FR Doc. 05–12938 of July 6, 2005 (70 FR 39022), we identified errors to Addendum A and Addendum B that are corrected under ''Correction of Addenda Errors'' in section III of this document. These corrections are effective as if they had been included in the document published July 6, 2005.

II. Delay in Implementation Date

On March 4, 2005, we published a proposed rule (70 FR 10746) to implement a CAP program, as required by section 1847B of the Act, as added by section 303(d) of the MMA, for certain Medicare Part B drugs not paid on a cost or prospective payment system basis. In response to the proposed rule, commenters expressed concern about the short timeframe for implementation of the CAP, that is, the proposed January 1, 2006 effective date stated in the July 6, 2005 interim final rule. These commenters suggested we delay the effective date of the CAP to allow us to fully structure the CAP to meet congressional objectives and benefit physicians without compromising beneficiary access to drug therapies and treatment.

We responded to those comments in the July 6, 2005 interim final rule (70 FR 39025) by stating that we recognized that the timeframe for implementation was ambitious but we believed that the regulatory framework provided a firm basis for implementing the CAP in January 2006.

We also stated that the statute requires that we coordinate the physicians' election to participate in the CAP with the Medicare Participating Physician Process described in section 1842(h) of the Act.

However, upon further consideration of these comments, as well as additional feedback we have received from potential participants in the program, we have concluded that more time is needed to further refine the program before implementation. After reviewing public comments, we agree that a short delay in implementing the CAP will allow us to improve the efficiency of the program and increase interest in participating in the program. Therefore, in accordance with our authority to phase-in the program as appropriate during 2006, we are delaying implementation of the CAP. The CAP program will not begin on January 1, 2006, and the initial physician election process will not occur in 2005.

As noted above, we intend to implement the CAP during 2006 and we expect that the CAP program will begin sometime in or around July 2006. In addition, we expect the initial physician election period to occur in the spring of 2006 rather than in fall 2005. We consider the initial implementation of the CAP program to constitute an ''exigent circumstance'' for purposes of section 1847B(a)(5)(A)(i) of the Act and § 414.908(a)(2) of our regulations, which allow for a physician election period at times other than the regular, annual election period. We are specifying the initial election period as an ''exigent circumstance'' because we intend the program to run on a calendar year basis, as stated in the July 2005 interim final rule, after the initial implementation of the CAP in 2006. In later years, the annual CAP election period will be coordinated with the annual Medicare Participating Physician Enrollment Process described in section 1842(h) of the Act, which occurs in the fall of each year, as specified in the July 2005 interim final rule.

We believe that, after the initial election period in 2006, an annual election period that ends on November 15 before the beginning of each CAP year is still necessary to allow time for the carrier, the designated carrier, the vendors, and our claims processing system to complete tasks in preparation for that CAP year. We expect to include the dates of the initial physician election period in the final rule. Physicians will then be provided with a second election period in 2006 for participation in the CAP in 2007.

In the July 6, 2005 interim final rule, we stated in several other places in the preamble that the CAP would begin on January 1, 2006.

For example, we referred to a January 1, 2006 start date in our discussion of the activities that would be necessary to implement the CAP on that date. These included CAP operations, analysis and coding of the CAP claims processing system, and educating beneficiaries and physicians about the program. In the July 2005 interim final rule, we specified that in response to the March 2005 proposed rule, several commenters expressed concern about introducing the CAP so quickly without any formal testing or analysis of the program. Other commenters expressed concern about education and outreach efforts relating to the CAP. Our decision to suspend the current vendor bidding process and delay the start date of the CAP will allow time for refining CAP operations, additional testing of the claims processing system, and for further beneficiary, physician, and vendor applicant educational efforts. We believe this additional preparation time will greatly improve and ease the implementation process.

III. Correction of Addenda Errors

In the July 6, 2005 interim final rule, Addendum A ''Single Drug Category List'' does not include the column reflecting the weights assigned to each CAP drug that will be used in computing the composite bids. In this interim final rule, we are correcting the error by republishing Addendum A in its entirety, with the third column included. In addition, in Addendum B, ''New Drugs for CAP Bidding for 2006,'' we inadvertently included J7518 (mycophenolic acid), which should be excluded from this list because it is an orally administered immunosuppressive agent rather than a physician-administered drug. We are correcting this error by republishing Addendum B, which reflects the omission of J7518 (mycophenolic acid).

In FR Doc. 05–12938 of July 6, 2005 (70 FR 39022), make the following corrections:

1. On pages 39099 through 39102, Addendum A is corrected to read as follows:

ADDENDUM A—SINGLE DRUG CATEGORY LIST

HCPCS	Long description	Weight
J0150	INJECTION, ADENOSINE FOR THERAPEUTIC USE, 6 MG	0.00069338
J0152	INJECTION, ADENOSINE FOR DIAGNOSTIC USE, 30 MG	0.00455133
J0170	INJECTION, ADRENALIN, EPINEPHRINE, 1 ML AMPULE	0.00007823
J0207	INJECTION, AMIFOSTINE, 500 MG	0.00015946
J0215	INJECTION, ALEFACEPT, 0.5 MG	0.00082595
J0280	INJECTION, AMINOPHYLLIN, 250 MG	0.00081312
J0290	INJECTION, AMPICILLIN SODIUM, 500 MG	0.00012537

ADDENDUM A—SINGLE DRUG CATEGORY LIST—Continued

HCPCS	Long description	Weight
J0475	INJECTION, BACLOFEN, 10 MG	0.00024410
J0540	INJECTION, PENICILLIN G BENZATHINE AND PENICILLIN G PROCAINE, 1,200,000 UNITS	0.00007140
J0550	INJECTION, PENICILLIN G BENZATHINE AND PENICILLIN G PROCAINE, 2,400,000 UNITS	0.00001814
J0570	INJECTION, PENICILLIN G BENZATHINE, 1,200,000 UNITS	0.00004561
J0585	BOTULINUM TOXIN TYPE A, PER UNIT	0.03707810
J0587	BOTULINUM TOXIN TYPE B, PER 100 UNITS	0.00149279
J0600	INJECTION, EDETATE CALCIUM DISODIUM, 1000 MG	0.00004417
J0637	INJECTION, CASPOFUNGIN ACETATE, 5 MG	0.00008403
J0640	INJECTION, LEUCOVORIN CALCIUM, PER 50 MG	0.01054437
J0670	INJECTION, MEPIVACAINE HYDROCHLORIDE, PER 10 ML	0.00038034
J0690	INJECTION, CEFAZOLIN SODIUM, 500 MG	0.00042009
J0692	INJECTION, CEFEPIME HYDROCHLORIDE, 500 MG	0.00024611
J0696	INJECTION, CEFTRIAXONE SODIUM, PER 250 MG	0.00662508
J0698	INJECTION, CEFOTAXIME SODIUM, PER GM	0.00014738
J0702	INJECTION, BETAMETHASONE ACETATE & BETAMETHASONE SODIUM PHOSPHATE, PER 3 MG	0.00284989
J0704	INJECTION, BETAMETHASONE SODIUM PHOSPHATE, PER 4 MG	0.00056519
J0735	INJECTION, CLONIDINE HYDROCHLORIDE, 1 MG	0.00033826
J0800	INJECTION, CORTICOTROPIN, 40 UNITS	0.00360503
J0880	INJECTION, DARBEPOETIN ALFA, 5 MCG	0.11998845
J0895	INJECTION, DEFEROXAMINE MESYLATE, 500 MG	0.00024217
J1000	INJECTION, DEPO-ESTRADIOL CYPIONATE, 5 MG	0.00020815
J1020	INJECTION, METHYLPREDNISOLONE ACETATE, 20 MG	0.00126125
J1030	INJECTION, METHYLPREDNISOLONE ACETATE, 40 MG	0.00587530
J1040	INJECTION, METHYLPREDNISOLONE ACETATE, 80 MG	0.00522812
J1051	INJECTION, MEDROXYPROGESTERONE ACETATE, 50 MG	0.00006464
J1094	INJECTION, DEXAMETHASONE ACETATE, 1 MG	0.00347947
J1100	INJECTION, DEXAMETHASONE SODIUM PHOSPHATE, 1MG	0.05440123
J1190	INJECTION, DEXRAZOXANE HYDROCHLORIDE, PER 250 MG	0.00002421
J1200	INJECTION, DIPHENHYDRAMINE HCL, 50 MG	0.00214443
J1212	INJECTION, DMSO, DIMETHYL SULFOXIDE, 50%, 50 ML	0.00008395
J1245	INJECTION, DIPYRIDAMOLE, PER 10 MG	0.00379554
J1250	INJECTION, DOBUTAMINE HYDROCHLORIDE, PER 250 MG	0.00052679
J1260	INJECTION, DOLASETRON MESYLATE, 10 MG	0.01720675
J1335	INJECTION, ERTAPENEM SODIUM, 500 MG	0.00013138
J1440	INJECTION, FILGRASTIM (G–CSF), 300 MCG	0.00191741
J1441	INJECTION, FILGRASTIM (G–CSF), 480 MCG	0.00403536
J1450	INJECTION FLUCONAZOLE, 200 MG	0.00001593
J1580	INJECTION, GARAMYCIN, GENTAMICIN, 80 MG	0.00039560
J1600	INJECTION, GOLD SODIUM THIOMALATE, 50 MG	0.00005560
J1626	INJECTION, GRANISETRON HYDROCHLORIDE, 100 MCG	0.01469700
J1631	INJECTION, HALOPERIDOL DECANOATE, PER 50 MG	0.00020506
J1642	INJECTION, HEPARIN SODIUM, (HEPARIN LOCK FLUSH), PER 10 UNITS	0.06362003
J1644	INJECTION, HEPARIN SODIUM, PER 1000 UNITS	0.00351209
J1645	INJECTION, DALTEPARIN SODIUM, PER 2500 IU	0.00011417
J1650	INJECTION, ENOXAPARIN SODIUM, 10 MG	0.00134336
J1655	INJECTION, TINZAPARIN SODIUM, 1000 IU	0.00046724
J1710	INJECTION, HYDROCORTISONE SODIUM PHOSPHATE, 50 MG	0.00006029
J1720	INJECTION, HYDROCORTISONE SODIUM SUCCINATE, 100 MG	0.00013201
J1745	INJECTION INFLIXIMAB, 10 MG	0.02736596
J1750	INJECTION, IRON DEXTRAN, 50 MG	0.00244189
J1756	INJECTION, IRON SUCROSE, 1 MG	0.01017283
J1885	INJECTION, KETOROLAC TROMETHAMINE, PER 15 MG	0.00326961
J1940	INJECTION, FUROSEMIDE, 20 MG	0.00064751
J1956	INJECTION, LEVOFLOXACIN, 250 MG	0.00008548
J2001	INJECTION, LIDOCAINE HCL FOR INTRAVENOUS INFUSION, 10 MG	0.00076795
J2010	INJECTION, LINCOMYCIN HCL, 300 MG	0.00061870
J2150	INJECTION, MANNITOL, 25% IN 50 ML	0.00028934
J2260	INJECTION, MILRINONE LACTATE, 5 MG	0.00004912
J2300	INJECTION, NALBUPHINE HYDROCHLORIDE, PER 10 MG	0.00026092
J2324	INJECTION, NESIRITIDE, 0.25 MG	0.00027147
J2353	INJECTION, OCTREOTIDE, DEPOT FORM FOR INTRAMUSCULAR INJECTION, 1 MG	0.00193262
J2354	INJECTION, OCTREOTIDE, NON-DEPOT SUBCUTANEOUS OR INTRAVENOUS INJECTION, 25 MCG	0.00008332
J2405	INJECTION, ONDANSETRON HYDROCHLORIDE, PER 1 MG	0.01360054
J2430	INJECTION, PAMIDRONATE DISODIUM, PER 30 MG	0.00155307
J2505	INJECTION, PEGFILGRASTIM, 6 MG	0.00064498
J2550	INJECTION, PROMETHAZINE HCL, 50 MG	0.00068031
J2680	INJECTION, FLUPHENAZINE DECANOATE, 25 MG	0.00014971
J2765	INJECTION, METOCLOPRAMIDE HCL, 10 MG	0.00011029
J2780	INJECTION, RANITIDINE HYDROCHLORIDE, 25 MG	0.00087713
J2820	INJECTION, SARGRAMOSTIM (GM–CSF), 50 MCG	0.00215849
J2912	INJECTION, SODIUM CHLORIDE, 0.9%, PER 2 ML	0.00673579
J2916	INJECTION, SODIUM FERRIC GLUCONATE COMPLEX IN SUCROSE INJECTION, 12.5 MG	0.00060556

ADDENDUM A—SINGLE DRUG CATEGORY LIST—Continued

HCPCS	Long description	Weight
J2920	INJECTION, METHYLPREDNISOLONE SODIUM SUCCINATE, 40 MG	0.00030935
J2930	INJECTION, METHYLPREDNISOLONE SODIUM SUCCINATE, 125 MG	0.00076469
J2997	INJECTION, ALTEPLASE RECOMBINANT, 1 MG	0.00012123
J3260	INJECTION, TOBRAMYCIN SULFATE, 80 MG	0.00018119
J3301	INJECTION, TRIAMCINOLONE ACETONIDE, PER 10 MG	0.02146050
J3302	INJECTION, TRIAMCINOLONE DIACETATE, PER 5 MG	0.00171576
J3303	INJECTION, TRIAMCINOLONE HEXACETONIDE, PER 5 MG	0.00093708
J3315	INJECTION, TRIPTORELIN PAMOATE, 3.75 MG	0.00000707
J3370	INJECTION, VANCOMYCIN HCL, 500 MG	0.00083391
J3396	INJECTION, VERTEPORFIN, 0.1 MG	0.05387196
J3410	INJECTION, HYDROXYZINE HCL, 25 MG	0.00040617
J3420	INJECTION, VITAMIN B–12 CYANOCOBALAMIN, UP TO 1000 MCG	0.01191674
J3475	INJECTION, MAGNESIUM SULFATE, PER 500 MG	0.00107478
J3480	INJECTION, POTASSIUM CHLORIDE, PER 2 MEQ	0.00213669
J3487	INJECTION, ZOLEDRONIC ACID, 1 MG	0.00333297
J7030	INFUSION, NORMAL SALINE SOLUTION , 1000 CC	0.00101862
J7040	INFUSION, NORMAL SALINE SOLUTION, (500 STERILE ML=1 UNIT)	0.00240866
J7042	5% DEXTROSE/NORMAL SALINE (500 ML = 1 UNIT)	0.00049401
J7050	INFUSION, NORMAL SALINE SOLUTION , 250 CC	0.00983951
J7051	STERILE SALINE OR WATER, 5 CC	0.00695398
J7060	5% DEXTROSE/WATER (500 ML = 1 UNIT)	0.00101887
J7070	INFUSION, D5W, 1000 CC	0.00015744
J7120	RINGERS LACTATE INFUSION, 1000 CC	0.00016820
J7317	SODIUM HYALURONATE, PER 20 TO 25 MG DOSE FOR INTRA-ARTICULAR INJECTION	0.00189786
J7320	HYLAN G–F 20, 16 MG, FOR INTRA ARTICULAR INJECTION	0.00148437
J9000	DOXORUBICIN HCL, 10 MG	0.00233616
J9001	DOXORUBICIN HYDROCHLORIDE, ALL LIPID FORMULATIONS, 10 MG	0.00032228
J9031	BCG (INTRAVESICAL) PER INSTILLATION	0.00048801
J9040	BLEOMYCIN SULFATE, 15 UNITS	0.00003692
J9045	CARBOPLATIN, 50 MG	0.00564705
J9050	CARMUSTINE, 100 MG	0.00000881
J9060	CISPLATIN, POWDER OR S0LUTION, PER 10 MG	0.00094491
J9062	CISPLATIN, 50 MG	0.00025190
J9065	INJECTION, CLADRIBINE, PER 1 MG	0.00008065
J9070	CYCLOPHOSPHAMIDE, 100 MG	0.00062098
J9080	CYCLOPHOSPHAMIDE, 200 MG	0.00004921
J9090	CYCLOPHOSPHAMIDE, 500 MG	0.00008048
J9091	CYCLOPHOSPHAMIDE, 1.0 GRAM	0.00005001
J9092	CYCLOPHOSPHAMIDE, 2.0 GRAM	0.00000525
J9093	CYCLOPHOSPHAMIDE, LYOPHILIZED, 100 MG	0.00091804
J9094	CYCLOPHOSPHAMIDE, LYOPHILIZED, 200 MG	0.00009103
J9095	CYCLOPHOSPHAMIDE, LYOPHILIZED, 500 MG	0.00017529
J9096	CYCLOPHOSPHAMIDE, LYOPHILIZED, 1.0 GRAM	0.00013845
J9097	CYCLOPHOSPHAMIDE, LYOPHILIZED, 2.0 GRAM	0.00001347
J9098	CYTARABINE LIPOSOME, 10 MG	0.00000809
J9100	CYTARABINE, 100 MG	0.00012887
J9110	CYTARABINE, 500 MG	0.00002056
J9130	DACARBAZINE, 100 MG	0.00009340
J9140	DACARBAZINE, 200 MG	0.00006957
J9150	DAUNORUBICIN, 10 MG	0.00000485
J9170	DOCETAXEL, 20 MG	0.00254788
J9178	INJECTION, EPIRUBICIN HCL, 2 MG	0.00120764
J9181	ETOPOSIDE, 10 MG	0.00229277
J9182	ETOPOSIDE, 100 MG	0.00052610
J9185	FLUDARABINE PHOSPHATE, 50 MG	0.00030358
J9190	FLUOROURACIL, 500 MG	0.00392446
J9200	FLOXURIDINE, 500 MG	0.00000405
J9201	GEMCITABINE HCL, 200 MG	0.00491490
J9202	GOSERELIN ACETATE IMPLANT, PER 3.6 MG	0.00285868
J9206	IRINOTECAN, 20 MG	0.00316077
J9208	IFOSFAMIDE, 1 GM	0.00007818
J9209	MESNA, 200 MG	0.00036520
J9211	IDARUBICIN HYDROCHLORIDE, 5 MG	0.00000315
J9213	INTERFERON, ALFA–2A, RECOMBINANT, 3 MILLION UNITS	0.00008006
J9214	INTERFERON, ALFA–2B, RECOMBINANT, 1 MILLION UNITS	0.00668813
J9219	LEUPROLIDE ACETATE IMPLANT, 65 MG	0.00006464
J9245	INJECTION, MELPHALAN HYDROCHLORIDE, 50 MG	0.00000157
J9250	METHOTREXATE SODIUM, 5 MG	0.00184935
J9260	METHOTREXATE SODIUM, 50 MG	0.00050963
J9263	INJECTION, OXALIPLATIN, 0.5 MG	0.07249359
J9265	PACLITAXEL, 30 MG	0.00551428
J9268	PENTOSTATIN, PER 10 MG	0.00000639

ADDENDUM A—SINGLE DRUG CATEGORY LIST—Continued

HCPCS	Long description	Weight
J9280	MITOMYCIN, 5 MG	0.00004038
J9290	MITOMYCIN, 20 MG	0.00003448
J9291	MITOMYCIN, 40 MG	0.00006085
J9293	INJECTION, MITOXANTRONE HYDROCHLORIDE, PER 5 MG	0.00024882
J9310	RITUXIMAB, 100 MG	0.00405692
J9320	STREPTOZOCIN, 1 GM	0.00000666
J9340	THIOTEPA, 15 MG	0.00002429
J9350	TOPOTECAN, 4 MG	0.00018095
J9355	TRASTUZUMAB, 10 MG	0.00538210
J9360	VINBLASTINE SULFATE, 1 MG	0.00035474
J9370	VINCRISTINE SULFATE, 1 MG	0.00019564
J9375	VINCRISTINE SULFATE, 2 MG	0.00011406
J9390	VINORELBINE TARTRATE, PER 10 MG	0.00109985
J9395	INJECTION, FULVESTRANT, 25 MG	0.00125472
J9600	PORFIMER SODIUM, 75 MG	0.00000029
Q0136	INJECTION, EPOETIN ALPHA, (FOR NON ESRD USE), PER 1000 UNITS	0.24898913
Q0137	INJECTION, DARBEPOETIN ALFA, 1 MCG (NON-ESRD USE)	0.03803750
Q3025	INJECTION, INTERFERON BETA–1A, 11 MCG FOR INTRAMUSCULAR USE	0.00077522

2. On page 39102, Addendum B is corrected to read as follows:

ADDENDUM B—NEW DRUGS FOR CAP BIDDING FOR 2006

CODE	2005 Description
J0128	Abarelix injection.
J0180	Agalsidase beta injection.
J0878	Daptomycin injection.
J1931	Laronidase injection.
J2357	Omalizumab injection.
J2469	Palonosetron HCl.
J2794	Risperidone, long acting.
J9035	Bevacizumab injection.
J9041	Bortezomib injection.
J9055	Cetuximab injection.
J9305	Pemetrexed injection.

IV. Waiver of Delay in Effective Date

We ordinarily provide an effective date 30 days after the publication of an interim final rule in the **Federal Register**. We can waive this delay, however, if we find good cause that it is impracticable, unnecessary, or contrary to the public interest and incorporate a statement of the finding and the reasons for it into the notice issued.

We find a delay in the effectiveness of this rule unnecessary because this rule merely provides further clarification of and technical corrections to the interim final rule with comment published July 6, 2005. We also find that a delay in the effectiveness of this interpretation would be contrary to the public interest: a delay in the effectiveness of this rule would defeat the purpose of this rule, which is to delay the implementation of the CAP in order to consider further public comment and issue a final rule before beginning this major new payment system. Therefore, for all of these reasons, we find good cause to waive the delay in the effective date of this rule. It will take effect on the same day as the July 6, 2005 interim final rule with comment.

V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

VI. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), 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.

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). This rule does not reach the economic threshold and thus is not considered a major rule.

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 small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 million to $29 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined that this rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Core-Based Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This rule will have no consequential effect on the governments mentioned or on the private sector.

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. Since this regulation does not impose any costs on State or local governments, the requirements of E.O. 13132 are not applicable.

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

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: August 23, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: August 31, 2005.

Michael O. Leavitt,

Secretary.

[FR Doc. 05–17655 Filed 9–1–05; 9:14 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket No. FEMA–7891]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Final rule.

SUMMARY: This rule identifies communities, where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP), that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur and a notice of this will be provided by publication in the **Federal Register** on a subsequent date.

EFFECTIVE DATES: The effective date of each community's scheduled suspension is the third date (''Susp.'') listed in the third column of the following tables.

ADDRESSES: If you want to determine whether a particular community was suspended on the suspension date, contact the appropriate FEMA Regional Office or the NFIP servicing contractor.

FOR FURTHER INFORMATION CONTACT: Michael M. Grimm, Mitigation Division, 500 C Street, SW., Room 412, Washington, DC 20472, (202) 646–2878.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase flood insurance which is generally not otherwise available. In return, communities agree to adopt and administer local floodplain management aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage as authorized under the NFIP, 42 U.S.C. 4001 *et seq.*; unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59 *et seq.* Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. However, some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue their eligibility for the sale of insurance. A notice withdrawing the suspension of the communities will be published in the **Federal Register**.

In addition, FEMA has identified the Special Flood Hazard Areas (SFHAs) in these communities by publishing a Flood Insurance Rate Map (FIRM). The date of the FIRM, if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may legally be provided for construction or acquisition of buildings in identified SFHAs for communities not participating in the NFIP and identified for more than a year, on FEMA's initial flood insurance map of the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column. The Administrator finds that notice and public comment under 5 U.S.C. 553(b) are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community receives 6-month, 90-day, and 30-day notification letters addressed to the Chief Executive Officer stating that the community will be suspended unless the required floodplain management measures are met prior to the effective suspension date. Since these notifications were made, this final rule may take effect within less than 30 days.

National Environmental Policy Act

This rule is categorically excluded from the requirements of 44 CFR Part 10, Environmental Considerations. No environmental impact assessment has been prepared.

Regulatory Flexibility Act

The Administrator has determined that this rule is exempt from the requirements of the Regulatory Flexibility Act because the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed no longer comply with the statutory requirements, and after the effective date, flood insurance will no longer be available in the communities unless remedial action takes place.

Regulatory Classification

This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Paperwork Reduction Act

This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

List of Subjects in 44 CFR Part 64

Flood insurance, Floodplains.

■ Accordingly, 44 CFR part 64 is amended as follows:

PART 64—[AMENDED]

■ 1. The authority citation for Part 64 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp.; p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp.; p. 376.