To a certain extent because of their separation from their normal parents, the therapists and staff themselves often become surrogates for parental authority. When those therapists and medical staff are involved in a research project, the child's assent or failure to object may be influenced by the surrogate parent relationship.

With regard to parents there are certain obvious impacts on both the family unit and the parent that result from a child's illness. First, the emotional impact of a serious illness in the family may lead to a breakdown of the judgmental and perceptive relationships within the normal family unit. To a certain extent, the sick child becomes a burden that parents may not be capable of assuming without some diminishing of normal parental judgment and discretion. This is especially true in situations in which the child must be confined to an institution in order to obtain therapy or treatment. It is also true of those situations in which therapy or treatment at home is especially difficult and disruptive. Second, the parent of the sick child will in most instances have a long, intimate, and even emotional involvement with those who provide therapy for the child. As amply demonstrated in some of the filmed informed consent sequences presented to the Commission, that emotional involvement with the therapist may well have a severe and in fact even overriding inpact on the parents' judgment with regard to granting permission for the participation of their child in a research project.

In conclusion then both the principle of beneficence, and the adverse impact on the other protective mechanisms require that this Commission afford sick children greater protection than that afforded to children at large.

3. *The Distinctions Attempted in Both Sets of Deliberations are Shams and There is No Legal, Ethical or Social Basis for Subjecting Sick Children to More Than Minimal Risk Merely Because a Foreseeable Benefit Might Accrue to an Identifiable Class of Children in the Future.*

In its two sets of deliberations, the Commission has attempted to present a shopping list of reasons in support of Recommendation (5). Each of these shall be dealt with separately, below.

First, the Commission notes that "the scope of parental authority routinely covers a child's participation in many activities in which risk is more than minimal, and yet benefit is questionable (involvement in skiing and contact sports are two examples among many)." Without concurring in the judgment of the Commission that benefit in skiing and contact sports is questionable, it is clear to me that this same rationale holds true for normal children as well as sick children. Thus, I perceive no basis for making any distinction between the two classes of children on the basis of that statement.

Second, the Commission notes that it was "impressed by reported examples of diagnostic therapeutic and preventive measures that might well have been derived from research involving risks that, while minor, would be considered more than minimal." Again, that rationale provides no basis for segregating children into separate classes. The rationale is strictly utilitarian and is not specifically supported in the record. Moreover, at no point does the Commission require that such research be carried out only if normal children would not be scientifically appropriate subjects. In the absence of such a limitation, I do not believe a strictly utilitarian rationale can provide adequate justification for a policy creating a doubly disadvantaged class of children.

Third, the Commission suggests that more than minimal risk is a condition that is "normal" for sick children. My problems with that characterization have been expressed above and will not be repeated here.

Finally, both sets of Commission deliberations conclude that "foreseeable benefits in the future to an identifiable class of children may justify a minor increment of risk to research subjects." That statement can be used to justify large quantities of applied research utilizing sick as opposed to normal children. The statement itself is without legal, ethical or social justification. If such justification did exist, it could be applied equally as well to normal children. In a situation in which "conservative" limits are placed on the participation of normal children, relaxation of those limits for sick children constitutes a specific mandate and direction to shift the risks and burdens of research from children in general to those who, by nature of their illness, are least, and not most, appropriate research subjects.

Comment by Dr. Ryan, Chairman of the Commission

In spite of the diversity of views reflected in the foregoing statements, our recommendations were adopted almost unanimously. The dissenting statement of Commissioner Turtle reflects a sharp disagreement, however, and requires some comment since it is based, I believe, on a misunderstanding of Recommendation (5).

The Commission has adopted a conservative definition of "minimal risk," i.e., the risk of harm that is normally encountered in the daily lives, or in the routine medical or psychological examination, of healthy children. Virtually the entire Commission is in agreement that a "minor" or "slight" additional risk over that normally encountered may ethically be presented in very limited circumstances by research not intended to benefit directly the children who are subjects. These limited circumstances are commensurability of experience, likelihood of yielding generalizable knowledge about the subjects' disorder, and importance of that knowledge for understanding or treating such disorder. Further, provision must be made when appropriate, for the participation of parents in such research involving their children.

Recommendation (5) contemplates research into the nature and treatment of disorders that specifically afflict children. The limited circumstances under which such research may be approved under Recommendation (5) clearly indicate that the research must be related to the disorder or condition affecting those subjects who are involved. Such research cannot by its very nature be conducted on normal subjects. Accordingly, Mr. Turtle's statement that the Commission's recommendations require research presenting more than minimal risk to be carried out on sick children merely because they are already subject to such risk, and his contention that the recommendation would shift involvement in such research from normal to sick children, are both incorrect. The Commission's intention in Recommendation (5), and the likely effect of this recommendation, are clearly not to encourage any unnecessary involvement of sick children in research, but rather to permit the conduct of research intended to develop important knowledge of disease states from which certain children suffer and for which research they are the only appropriate subjects.

[FR Doc. 78-657 Filed 1-12-78; 8:45 am]

federal register

FRIDAY, JANUARY 13, 1978

PART IV

DEPARTMENT OF LABOR

Employment Standards Administration

■

MINIMUM WAGES FOR FEDERAL AND FEDERALLY ASSISTED CONSTRUCTION

General Wage Determination Decisions

[4510-27]

DEPARTMENT OF LABOR

Employment Standards Administration

MINIMUM WAGES FOR FEDERAL AND FEDERALLY ASSISTED CONSTRUCTION

General Wage Determination Decisions

General Wage Determination Decisions of the Secretary of Labor specify, in accordance with applicable law and on the basis of information available to the Department of Labor from its study of local wage conditions and from other sources, the basic hourly wage rates and fringe benefit payments which are determined to be prevailing for the described classes of laborers and mechanics employed in construction activity of the character and in the localities specified therein.

The determinations in these decisions of such prevailing rates and fringe benefits have been made by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR 1.1 (including the statutes listed at 36 FR 306 following Secretary of Labor's Order No. 24-70) containing provisions for the payment of wages which are dependent upon determination by the Secretary of Labor under the Davis-Bacon Act; and pursuant to the provisions of Part 1 of Subtitle A of Title 29 of Code of Federal Regulations, Procedure for Predetermination of Wage Rates, (37 FR 21138) and of Secretary of Labor's Orders 12-71 and 15-71 (36 FR 8755, 8756). The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in effective date as prescribed in that section, because the necessity to issue construction industry wage determination frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General Wage Determination Decisions are effective from their date of publication in the FEDERAL REGISTER without limitation as to time and are to be used in accordance with the provisions of 29 CFR Parts 1 and 5. Accordingly, the applicable decision together with any modifications issued subsequent to its publication date shall be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR, Part 5. The wage rates contained therein shall be the minimum paid under such contract by contractors and subcontractors on the work.

MODIFICATIONS AND SUPERSEDEAS DECISIONS TO GENERAL WAGE DETERMINATION DECISIONS

Modifications and Supersedeas Decisions to General Wage Determination Decisions are based upon information obtained concerning changes in prevailing hourly wage rates and fringe benefit payments since the decisions were issued.

The determinations of prevailing rates and fringe benefits made in the Modifications and Supersedeas Decisions have been made by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR 1.1 (including the statutes listed at 36 FR 306 following Secretary of Labor's Order No. 24-70) containing provisions for the payment of wages which are dependent upon determination by the Secretary of Labor under the Davis-Bacon Act; and pursuant to the provisions of Part 1 of Subtitle A of Title 29 of Code of Federal Regulations, Procedure for Predetermination of Wage Rates (37 FR 21138) and of Secretary of Labor's Orders 13-71 and 15-71 (36 FR 8755, 8756). The prevailing rates and fringe benefits determined in foregoing General Wage Determination Decisions, as hereby modified, and/or superseded shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged in contract work of the character and in the localities described therein.

Modifications and Supersedeas Decisions are effective from their date of publication in the FEDERAL REGISTER without limitation as to time and are to be used in accordance with the provisions of 29 CFR Parts 1 and 5.

Any person, organization, or governmental agency having an interest in the wages determined as prevailing is encouraged to submit wage rate information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Office of Special Wage Standards, Division of Wage Determinations, Washington, D.C. 20210. The cause for not utilizing the rule-making procedures prescribed in 5 U.S.C. 553 has been set forth in the original General Wage Determination Decision.

MODIFICATIONS TO GENERAL WAGE DETERMINATION DECISIONS

The numbers of the decisions being modified and their dates of publication in the FEDERAL REGISTER are listed with each State.

Alabama:	
AL77-1025	Mar. 4, 1977.
AL77-1040	Apr. 1, 1977.
Arkansas:	
AR77-4173	Aug. 19, 1977.
AR77-4285; AR77-4286; AR77-4287; AR77-4288	Sept. 30, 1977.
AL77-4290	Nov. 11, 1977.
Idaho	
ID77-5088	Oct. 7, 1977.
Mississippi:	
MS76-1004	Jan. 9, 1976.
MS77-1069	May 20, 1977.
MS77-1078	June 17, 1977.
Nevada:	
NV77-5072	July 8, 1977.
NV77-5077; NV77-5085; NV77-5089	Sept. 23, 1977.
Oklahoma:	
OK77-4273; OK77-4274	Sept. 30, 1977.
Texas:	
TX76-4039	Feb. 13, 1976.
TX77-4193; TX77-4197	Aug. 19, 1977.
TX77-4221	Sept. 23, 1977.
TX77-4236; TX77-4237; TX77-4238; TX77-4239; TX77-4240; TX77-4241; TX77-4242; TX77-4243; TX77-4244; TX77-4245; TX77-4246; TX77-4247; TX77-4248; TX77-4249; TX77-4250; TX77-4251; TX77-4252; TX77-4254; TX77-4256; TX77-4257; TX77-4258; TX77-4259; TX77-4260; TX77-4261; TX77-4262; TX77-4263; TX77-4264; TX77-4265; TX77-4280	Sept. 30, 1977.
TX77-4289	Oct. 21, 1977.
Utah:	
UT77-5075	Aug. 5, 1977.
Wisconsin:	
WI77-2102	July 15, 1977.
WI77-2126	Aug. 26, 1977.

SUPERSEDEAS DECISIONS TO GENERAL WAGE DETERMINATION DECISIONS

The numbers of the decisions being superseded and their dates of publication in the FEDERAL REGISTER are listed with each State.

Supersedeas Decision numbers are in parentheses following the numbers of the decisions being superseded.

Texas:	
TX77-4201 (TX77-4004)	Aug. 19, 1977.
TX77-4222 (TX77-4003)	Sept. 23, 1977.
TX77-4253 (TX77-4002)	Sept. 30, 1977.

Signed at Washington, D.C., this 6th day of January 1978.

RAY J. DOLAN,
Assistant Administrator, Wage and Hour Division.

MODIFICATIONS P. 1

Decision	Basic Hourly Rates	Fringe Benefits Payments: H & W	Pensions	Vacation	Education and/or Appr. Tr.
Decision # AL77-1025 - Mod. #3 (42 FR-15277 - March 4, 1977) Lawrence, Limestone and Morgan Counties, Alabama					
CHANGE:					
Plumbers, pipefitters, steamfitters: Lawrence County (Eastern Portion of Co.., North from intersection of State Rt. 33 and Rt. 20 to Wheeler Lake including Moulton and Wren, excluding Bankhead National Park) Limestone Co. & Morgan Co.,	$10.50	.50	.55		.10
Decision # AL77-1040 - Mod. #5 (42 FR-17752 - April 1, 1977) Madison County, Alabama					
CHANGE:					
Plumbers & pipefitters	$ 10.50	.50	.55		.10
Power Equipment Operators:					
Group A	9.98	.40	.40		
Group B	8.64	.40	.40		
Group C	7.92	.40	.40		

MODIFICATIONS P. 2

Decision	Basic Hourly Rates	Fringe Benefits Payments: H & W	Pensions	Vacation	Education and/or Appr. Tr.
DECISION NO. AR77-4173 - Mod. #4 (42 FR 42063 - August 19, 1977) Jefferson County, Arkansas					
CHANGE:					
ASBESTOS WORKERS	$10.70	.50	.70		.02
PLASTERERS	9.25				.02
DECISION NO. AR77-4285 - Mod. #3 (42 FR 52898 - September 30, 1977) Garland, Hot Springs and Clark Counties, Arkansas					
CHANGE:					
ASBESTOS WORKERS	10.70	.50	.70		.02
PLASTERERS	9.25				.02
BRICKLAYERS	8.40	.40	.35		.04
DECISION NO. AR77-4286 - Mod. #2 (42 FR 52900 - September 30, 1977) Union and Ouachita Counties, Arkansas					
CHANGE:					
ASBESTOS WORKERS	10.70	.50	.70		.02
PLASTERERS	9.25				.02
BRICKLAYERS	8.40	.40	.35		.04
DECISION NO. AR77-4287 - Mod. #5 (42 FR 52903 - September 30, 1977) Pulaski County, Arkansas					
CHANGE:					
ASBESTOS WORKERS	10.70	.50	.70		.02
PLASTERERS	9.25				.02
DECISION NO. AR77-4288 - Mod. #3 (42 FR 52901 - September 30, 1977) Sebastian, Crawford and Washington Counties, Arkansas					
CHANGE:					
PLASTERERS	9.25				.02
GLAZIERS (Washington County)	6.60				
DECISION NO. AR77-4290 - Mod. #2 (42 FR 58924 - November 11, 1977) Conway, Van Buren, Perry and Cleburne Counties, Arkansas					
CHANGE:					
ASBESTOS WORKERS	10.70	.50	.70		.02
PLASTERERS	9.25				.02

MODIFICATIONS P. 3

DECISION #ID77-5088 - Mod. #3 (42 FR 54709 - October 7, 1977) Statewide Idaho	Basic Hourly Rates	Fringe Benefits Payments H & W	Pensions	Vacation	Education and/or Appr. Tr.
Change:					
Asbestos Workers:					
Remaining Counties and Idaho County (south half)	$11.21	.84	$1.20		
Bricklayers; Stonemasons:					
Benewah, Bonner, Boundary, Kootenai, Shoshone Counties	12.00				
Ada, Adams, Boise, Canyon, Elmore, Gem, Owyhee, Payette, Valley, Washington Counties	11.15	.75	1.10		
Glaziers:					
Benewah, Clearwater, Idaho County (north of 46th Parallel), Latah, Lewis, Nez Perce Counties	9.53	.40	.35	b	
Ada, Adams, Boise, Canyon, Elmore, Gem, Gooding County (western part of County from a line running north and south through the eastern limits of the City of Bliss), Idaho County (southern part of County from a line running east and west through the north limits of Elk City), Owyhee, Payette, Valley, Washington Counties	10.00	.35	.30		.10
Marble Setters:					
Benewah, Bonner, Boundary, Kootenai, Shoshone Counties	12.00				
Ada, Adams, Boise, Canyon, Elmore, Gem, Owyhee, Payette, Valley, Washington Counties	11.15	.75	1.10		
Roofers:					
Ada, Adams, Boise, Camas, Canyon, Custer, Elmore, Gem, Idaho County (south of the 46th Parallel), Lemhi, Owyhee, Payette, Valley, Washington Counties:					
Roofers; Kettlemen	9.25	.60	.30	.50	
Roofers working with coal tar and pitch products	11.25	.60	.30	.50	

MODIFICATIONS P. 4

DECISION #ID77-5088 (Cont'd):	Basic Hourly Rates	Fringe Benefits Payments H & W	Pensions	Vacation	Education and/or Appr. Tr.
Add:					
Terrazzo Workers & Tile Setters: Benewah, Bonner, Boundary, Kootenai, Shoshone Counties	$12.00				
Change:					
Terrazzo Workers & Tile Setters:					
Clearwater, Idaho, Latah, Lewis, Nez Perce Counties	10.75	.65	.70		
Ada, Adams, Boise, Canyon, Elmore, Gem, Owyhee, Payette, Valley, Washington Counties	10.60	.75	1.10		
Decision # MS76-1004 - Mod. # 2 (41 FR-1695 - January 9, 1976) Washington, Warren, Sunflower, and Coahoma Counties, Mississippi.					
Change:					
Laborers:					
Laborers	2.65				
Asphalt raker	2.65				
Mason tender	2.65				
Mortar mixer	2.65				
Decision # MS77-1069 - Mod. # 1 (42 FR-26094 - May 20, 1977) Bolivar County, Mississippi.					
Change:					
Ironworkers, reinforcing	2.65				
Laborers:					
Laborers	2.65				
Mortar mixers	2.65				
Plasterers' tenders	2.65				
Truck Drivers	2.65				
Decision # MS77-1078 - Mod. #3 (42 FR-31044 - June 17,1977) Lowndes County (excluding Columbia Lock and Dam and Tennessee Tombigbee Project Mississippi					
CHANGE:					
Ironworkers, reinforcing	$ 10.00	.60	.815		.06

MODIFICATIONS P. 5

DECISION #NV77-5072 - Mod. #6 (42 FR 35562 - July 8, 1977) Nevada Test Site including Tonopah Test Range in Clark and Nye Counties, Nevada	Basic Hourly Rates	Fringe Benefits Payments: H & W	Pensions	Vacation	Education and/or Appr. Tr.
Change:					
Asbestos Workers:	$13.87	.85	$1.20		
Omit:					
Brick Tenders	10.02	.66	1.35		
Add:					
Mason Tenders	10.02	.66	1.35		
DECISION #NV77-5077 - Mod. #5 (42 FR 48662 - September 23, 1977) Statewide (does not include the Nevada Test Site and Tonopah Test Range, and highway construction in Douglas County), Nevada					
Change:					
Asbestos Workers:					
Elko, Eureka, White Pine Counties	$11.21	.84	$1.20		
Add:					
Brick Hod Carriers:					
Statewide excluding Clark, Esmeralda, Lincoln, Nye County (south half):					
Zone A: 0-35 miles from Courthouse in Reno, Nevada	9.60	.50	.90		.05
Zone B: 35-75 miles from Courthouse in Reno, Nevada	10.50	.50	.90		.05
Omit:					
Brick Tenders:					
Clark, Esmeralda, Lincoln, Nye County (south half)	10.02	.66	1.35		
Remaining Counties:					
Zone A: 0-35 miles from Courthouse in Reno, Nevada	9.60	.50	.90		.05
Zone B: 35-75 miles from Courthouse in Reno, Nevada	10.50	.50	.90		.05
Change:					
Bricklayers; Stonemasons:					
Clark, Esmeralda, Lincoln, Nye County (south of Hwy. #6)	12.27	.70	.60		.06
Marble Masons:					
Clark, Esmeralda, Lincoln, Nye County (south half)	12.27	.70	.60		.06
Remaining Counties and Nye County (north half)	11.45	.50	.60		.01

MODIFICATIONS P. 6

DECISION #NV77-5077 (Cont'd):

	Basic Hourly Rates	Fringe Benefits Payments: H & W	Pensions	Vacation	Education and/or Appr. Tr.
Add:					
Marble, Terrazzo, Tile Helpers:					
Clark, Esmeralda, Lincoln, Nye County (south half)	$9.65	.70	.60		
Remaining Counties and Nye County (north half)	6.87	.50	.60		.01
Mason Tenders:					
Clark, Esmeralda, Lincoln, Nye County (south half)	10.02	.66	1.35		
Plaster Hod Carriers:					
Statewide except Clark, Esmeralda, Lincoln, Nye County (south half):					
Plaster Hod Carriers serving Plasterers	10.75	.50	.90		
Plaster Hod Carriers working on any type of gun	11.35	.50	.90		
Plaster Tenders:					
Clark, Esmeralda, Lincoln, Nye County (south half)	11.12	.66	1.35		
Omit:					
Plasterer Tenders:					
Clark, Esmeralda, Lincoln, Nye County (south half)	11.12	.66	1.35		
Remaining Counties:					
Plasterer Tenders serving Plasterers	10.75	.50	.90		
Plasterer Tenders working on any type of gun	11.35	.50	.90		
Change:					
Soft Floor Layers:					
Clark, Esmeralda, Lincoln, Nye Counties	13.07	.65			.15
Terrazzo Workers; Tile Setters:					
Clark, Esmeralda, Lincoln, Nye County (south half)	12.27	.70	.60		.06

MODIFICATIONS P.7

DECISION #NV77-5085 - Mod. #3 (42 FR 48679 - September 23, 1977) Clark County (does not include the Nevada Test Site), Nevada	Basic Hourly Rates	Fringe Benefits Payments H & W	Pensions	Vacation	Education and/or Appr. Tr.
Omit:					
Brick Tenders	$10.02	.66	$1.35		
Change:					
Bricklayers; Stonemasons	12.27	.70	.60		.06
Marble Masons	12.27	.70	.60		.06
Add:					
Marble, Terrazzo, Tile Helpers	9.65	.70	.60		
Mason Tenders	10.02	.66	1.35		
Plaster Tenders	11.12	.66	1.35		
Omit:					
Plasterers' Tenders	11.12	.66	1.35		
Change:					
Soft Floor Layers	13.07	.65			.15
Terrazzo Workers; Tile Setters	12.27	.70	.60		.06
DECISION #NV77-5089 - Mod. #4 (42 FR 48665 - September 23, 1977) Washoe County, Nevada					
Add:					
Brick Hod Carriers:					
Zone 1: 0-35 miles from Courthouse in Reno, Nevada	$9.60	.50	.90		.05
Zone 2: 35-75 miles from Courthouse in Reno, Nevada	10.50	.50	.90		.05
Omit:					
Brick Tenders:					
Zone 1: 0-35 miles from Courthouse in Reno, Nevada	9.60	.50	.90		.05
Zone 2: 35-75 miles from Courthouse in Reno, Nevada	10.50	.50	.90		.05
Add:					
Marble, Terrazzo, Tile Helpers	6.87	.50	.60		.01
Plaster Hod Carriers:					
Plaster Hod Carrier serving Plasterers	10.75	.50	.90		
Plaster Hod Carrier working on any type of gun	11.35	.50	.90		
Omit:					
Plasterer Tenders:					
Plasterer Tender serving Plasterers	10.75	.50	.90		
Plasterer Tender working on any type of gun	11.35	.50	.90		

MODIFICATIONS P. 8

DECISION NO. OK77-4273 - Mod. #4 (42 FR 53091 - September 30, 1977) Oklahoma, Cleveland, Caddo, Grady, Canadian, Kingfisher, Logan, Lincoln, McClain, Seminole and Pottawatomie Counties, Oklahoma	Basic Hourly Rates	Fringe Benefits Payments H & W	Pensions	Vacation	Education and/or Appr. Tr.
CHANGE:					
SHEET METAL WORKERS	$10.82	.50	.84		.07
ELECTRICIANS:					
Zone I	10.35	.50	3%+.70		1%
Zone II	10.60	.50	3%+.70		1%
Zone III	10.85	.50	3%+.70		1%
CABLE SPLICERS:					
Zone I	10.60	.50	3%+.70		1%
Zone II	10.85	.50	3%+.70		1%
Zone III	11.10	.50	3%+.70		1%
BRICKLAYERS-STONEMASONS:					
Oklahoma, Cleveland, Canadian and McClain Counties	10.27	.50	.50		.05
Lincoln, Pottawatomie and Seminole Counties	9.85	.50	.30		.05
Logan County	10.27	.50	.50		.05
Caddo and Grady Counties	9.50	.50	.30		.10
OMIT FROM MODIFICATION #3 ISSUED IN FEDERAL REGISTER PUBLISHED DECEMBER 9, 1977:					
BRICKLAYERS	$10.27	.50	.50		.05
DECISION NO. OK77-4274 - Mod. #4 (42 FR 53094 - September 30, 1977) Garfield County, Oklahoma					
CHANGE:					
SHEET METAL WORKERS	10.82	.40	.84		.07
ELECTRICIANS:					
Zone I	10.35	.50	3%+.70		1%
Zone II	10.60	.50	3%+.70		1%
Zone III	10.85	.50	3%+.70		1%
CABLE SPLICERS:					
Zone I	10.60	.50	3%+.70		1%
Zone II	10.85	.50	3%+.70		1%
Zone III	11.10	.50	3%+.70		1%

MODIFICATIONS P. 9

DECISION #TX77-4193 - Mod. #4 (42 FR 42121 - August 19, 1977) - Bexar County, Texas
DECISION #TX77-4221 - Mod. #7 (42 FR 48723 - September 23, 1977) - Travis County, Texas
DECISION #TX77-4252 - Mod. #6 (42 FR 53147 - September 30, 1977) - Armstrong, Carson, Castro, Childress, Collingsworth, Dallam, Deaf Smith, Donley, Gray, Hansford, Hartley, Hemphill, Hutchinson, Lipscomb, Moore, Ochiltree, Oldham, Potter, Randall, Roberts, Sherman, Swisher & Wheeler Cos., Texas
DECISION #TX77-4254 - Mod. #6 (42 FR 53150 - September 30, 1977) - Bee, Kleberg & Nueces Cos., Texas
DECISION #TX77-4256 - Mod. #8 (42 FR 53154 - September 30, 1977) - Brazos County, Texas
DECISION #TX77-4258 - Mod. #8 (42 FR 53158 - September 30, 1977) - Galveston & Harris Cos., Texas
DECISION #TX77-4259 - Mod. #3 (42 FR 53161 - September 30, 1977) - Gregg County, Texas
DECISION #TX77-4261 - Mod. #5 (42 FR 53165 - September 30, 1977) - Lubbock County, Texas
DECISION #TX77-4262 - Mod. #2 (42 FR 53167 - September 30, 1977) - Smith County, Texas
DECISION #TX77-4263 - Mod. #3 (42 FR 53167 - September 30, 1977) - Taylor County, Texas
DECISION #TX77-4264 - Mod. #3 (42 FR 53168 - September 30, 1977) - Tom Green County, Texas
DECISION #TX77-4265 - Mod. #4 (42 FR 53169 - September 30, 1977) - Wichita County, Texas
DECISION #TX77-4280 - Mod. #3 (42 FR 53171 - September 30, 1977) - Cameron, Hidalgo, Starr & Willacy Counties, Texas
DECISION #TX77-4289 - Mod. #2 (42 FR 56311 - October 21, 1977) - Harrison County, Texas

Change Description of Work to Read as Follows:
Building Construction (does not include single family homes & garden type apartments up to & including 4 stories). (See current heavy & highway general wage determination for Paving & Utilities Incidental to Building Construction).

DECISION #TX76-4039 - Mod. #3 (41 FR 7014 - February 13, 1976) - Dimmit, Jim Hogg, LaSalle Maverick, Webb, Zapata & Zavala Counties, Texas
DECISION #TX77-4260 - Mod. #6 (42 FR 53162 - September 30, 1977) - Jefferson & Orange Counties, Texas

Change Description of Work to Read as Follows:
Building (including Residential) Construction

DECISION #TX77-4197 - Mod. #5 (42 FR 42127 - August 19, 1977) - Collin, Dallas, Denton, Ellis, Grayson, Hood, Hunt, Johnson, Kaufman, Palo Pinto, Rockwall, Tarrant & Wise Counties, Texas

Change Description of Work to Read as Follows:
Building Construction (does not include single family homes & garden type apartments up to & including 4 stories) & also does not include Dallas-Fort Worth Regional Airport. (see current heavy & highway general wage determination for Paving & Utilities Incidental to Building Construction).

DECISION #TX77-4257 - Mod. #4 (42 FR 53156 - September 30, 1977) - El Paso County, Texas

Change Description of Work to Read as Follows:
Building Construction (does not include single family homes & garden type apartments up to & including 4 stories). (see current heavy & highway general wage determination for Paving Incidental to Building Construction).

MODIFICATIONS P. 10

DECISION #TX77-4236 - Mod. #1 (42 FR 53118 - September 30, 1977) - Archer, Armstrong, Baylor, Briscoe, Carson, Castro, Childress, Clay, Collingsworth, Dallam, Deaf Smith, Donley, Gray, Hall, Hansford, Hardeman, Hartley, Hemphill, Hutchinson, Lipscomb, Montague, Moore, Ochiltree, Oldham, Parmer, Potter, Randall, Roberts, Sherman, Swisher, Wheeler, Wichita & Wilbarger Cos., Texas
DECISION #TX77-4237 - Mod. #1 (42 FR 53120 - September 30, 1977) - Bailey, Borden, Cochran, Cottle, Crosby, Dawson, Dickens, Fisher, Floyd, Foard, Gaines, Garza, Hale, Haskell, Hockley, Jones, Kent, King, Knox, Lamb, Lubbock, Lynn, Motley, Scurry, Shackelford, Stephens, Stonewall, Terry, Throckmorton, Yoakum & Young Cos., Texas
DECISION #TX77-4238 - Mod. #1 (42 FR 53122 - September 30, 1977) - Andrews, Brown, Callahan, Coke, Coleman, Comanche, Concho, Crane, Crockett, Eastland, Ector, Erath, Glasscock, Howard, Irion, Kimble, Loving, Martin, McCulloch, Menard, Midland, Mills, Mitchell, Nolan, Reagan, Runnels, San Saba, Schleicher, Sterling, Sutton, Taylor, Tom Green, Upton, Ward & Winkler Co., Texas
DECISION #TX77-4240 - Mod. #2 (42 FR 53126 - September 30, 1977) - Atascosa, Bandera, Bexar, Comal, Dimmit, Edwards, Frio, Guadalupe, Kendall, Kerr, Kinney, LaSalle, Maverick, McMullen, Medina, Real, Uvalde, Val Verde, Wilson & Zavala Cos., Texas
DECISION #TX77-4243 - Mod. #2 (42 FR 53132 - September 30, 1977) - Austin, Bastrop, Blanco, Burnet, Caldwell, Colorado, Fayette, Gillespie, Gonzales, Hays, Lee, Llano, Mason, Travis & Williamson Cos., Texas
DECISION #TX77-4247 - Mod. #1 (42 FR 53140 - September 30, 1977) - Bowie, Camp, Cass, Delta, Fannin, Franklin, Gregg, Harrison, Hopkins, Hunt, Kaufman, Lamar, Marion, Morris, Rains, Red River, Rusk, Smith, Titus, Upshur, Van Zandt & Wood Counties, Texas
DECISION #TX77-4249 - Mod. #1 (42 FR 53143 - September 30, 1977) - Brazos, Burleson, Grimes, Leon, Madison, Milam, Robertson, Walker & Washington Cos., Texas

Change Description of Work to Read as Follows:
Heavy (does not include tunnels & dams) & Highway (does not include building structures in rest area projects) Construction & Paving & Utilities Incidental to General Building Construction. This wage determination does not apply to any residential construction (single family homes & garden type apartments up to & including 4 stories).

DECISION #TX77-4239 - Mod. #2 (42 FR 53124 - September 30, 1977) - Brewster, Culberson, El Paso, Hudspeth, Jeff Davis, Pecos, Presidio, Reeves & Terrell Cos., Texas

Change Description of Work to Read as Follows:
Heavy (does not include tunnels & dams) & Highway (does not include building structures in rest area projects) Construction & Paving & Utilities Incidental to General Building Construction (not to be used for Utilities Incidental to General Building Construction in El Paso Co.). This wage determination does not apply to any residential construction (single family homes & garden type apartments up to & including 4 stories).

DECISION #TX77-4241 - Mod. #1 (42 FR 53128 - September 30, 1977) - Brooks, Cameron, Duval, Hidalgo, Jim Hogg, Kenedy, Starr, Webb, Willacy & Zapata Cos., Texas
DECISION #TX77-4242 - Mod. #2 (42 FR 53130 - September 30, 1977) - Aransas, Bee, Calhoun, DeWitt, Goliad, Jackson, Jim Wells, Karnes, Kleberg, Lavaca, Live Oak, Nueces, Refugio, San Patricio & Victoria Cos., Texas
DECISION #TX77-4248 - Mod. #1 - (42 FR 53142 - September 30, 1977) - Anderson, Angelina, Cherokee, Henderson, Houston, Jasper, Nacogdoches, Newton, Panola, Polk, Sabine, San Augustine, San Jacinto, Shelby, Trinity & Tyler Cos., Texas

Change Description of Work Read as Follows:
Heavy (does not include tunnels & dams) & Highway (does not include building structures in rest area projects) Construction & Incidental Shore Work & Paving & Utilities Incidental to General Building Construction. This wage determination does not apply to any residential construction (single family homes & garden type apartments up to & including 4 stories).

MODIFICATIONS P. 11

DECISION #TX77-4244 - Mod. #1 (42 FR 53134 - September 30, 1977) - Bell, Bosque, Coryell, Falls, Freestone, Hamilton, Hill, Lampasas, Limestone, McLennan & Navarro Cos., Texas

Change Description of Work to Read as Follows:
Heavy (does not include tunnels & dams) & Highway (does not include building structures in rest area projects) Construction & Paving & Utilities Incidental to General Building Construction (not to be used for Paving & Utilities Incidental to General Building Construction in Bell & Coryell Cos.). This wage determination does not apply to any residential construction (single family homes & garden type apartments up to & including 4 stories).

DECISION #TX77-4245 - Mod. #1 (42 FR 53136 - September 30, 1977) - Cooke, Denton, Hood, Jack, Johnson, Palo Pinto, Parker, Sommervell, Tarrant (does not include Dallas-Fort Worth Regional Airport) & Wise Cos., Texas

Change Description of Work to Read as Follows:
Heavy (does not include tunnels, dams & work performed on the site of water or sewage treatment facilities) & Highway (does not include building structures in rest area projects) Construction & Paving & Utilities Incidental to General Building Construction (not to be used for Utilities Incidental to General Building Construction in Tarrant Co.). This wage determination does not apply to any residential construction (single family homes & garden type apartments up to & including 4 stories).

DECISION #TX77-4246 - Mod. #1 (42 FR 53138 - September 30, 1977) - Collin, Dallas (does not include Dallas-Fort Worth Regional Airport), Ellis, Grayson & Rockwall Cos., Texas

Change Description of Work to Read as Follows:
Heavy (does not include tunnels, dams & work performed on the site of water or sewage treatment facilities) & Highway (does not include building structures in rest area projects) Construction & Paving & Utilities Incidental to General Building Construction. This wage determination does not apply to any residential construction (single family homes & garden type apartments up to & including 4 stories).

DECISION #TX4250 - Mod. #2 (42 FR 53144 - September 30, 1977) - Brazoria, Fort Bend, Galveston, Harris, Matagorda, Montgomery, Waller & Wharton Cos., Texas

Change Description of Work to Read as Follows:
Highway (does not include building structures in rest area projects) Construction, & Paving & Utilities Incidental to General Building Construction (not to be used for Paving & Utilities Incidental to General Building Construction on Galveston Island). This wage determination does not apply to any residential construction (single family homes & garden type apartments up to & including 4 stories).

DECISION #TX77-4251 - Mod. #1 (42 FR 53146 - September 30, 1977) - Chambers, Hardin, Jefferson, Liberty & Orange Cos., Texas

Change Description of Work to Read as Follows:
Heavy (does not include tunnels & dams & not to be used for Heavy Construction in Jefferson & Orange Cos.) & Highway (does not include building structures in rest area projects) Construction, Incidental Shore Work (not to be used for Incidental Shore Work in Jefferson & Orange Cos.) & Paving & Utilities Incidental to General Building Construction (not to be used for Paving & Utilities Incidental to General Building Construction in Jefferson & Orange Cos.). This wage determination does not apply to any residential construction (single family homes & garden type apartments up to & including 4 stories).

MODIFICATIONS P. 12

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
DECISION #UT77-5075 - Mod. #5 (42 FR 39884 - August 5, 1977) Statewide Utah					
Change:					
Asbestos Workers	$11.21	.84	$1.20		
Painters:					
Remaining part of State:					
Brush; Roller	9.70	.51	.30		.02
Brush (swing stage); Brush (steel and bridge); Spray; Sandblaster; Steeplejack	10.00	.51	.30		.02
Spray (swing stage); Spray, (steel and bridge); Sandblaster (swing stage)	10.25	.51	.30		.02
Wallcovering Hanger	9.95	.51	.30		.02
DECISION NO. WI77-2102 - MOD. #3 (42 FR 36781 - July 15, 1977) Statewide, Wisconsin					
Change:					
Bricklayers:					
Zone 1 - Barron, Buffalo, Burnett, Chippewa, Dunn, Eau Claire, Pepin, Polk, Rusk, St. Croix, and Sawyer Counties	$ 9.75	.65	.25		.05
Zone 4 - Green, Lafayette, and Rock Counties	10.38	.65	.30		
Zone 7 - Dane, Grant Iowa, and Richland Counties	9.29	.65	.60	.50	
Zone 9 - Columbia and Sauk Counties	10.10	.65	.30		
Zone 10 - Kenosha and Racine Counties	10.55	.60	.60	.50	.05
Zone 11 - Sheboygan County	9.20	.65	.40		.05
Zone 14 - Adams, Clark, Forest, Langlade, Lincoln, Marathon, Menominee, Oneida, Portage, Price, Taylor, Vilas, and Wood Counties	9.30	.65	.35		
Carpenters:					
Zone 1 - Ashland County					
Carpenters	8.59	.50	.30	.15	
Piledrivermen	8.79	.50	.30	.15	
Zone 4 - Green, Jefferson and Rock Counties					
Carpenters	10.28	.50	.50	.07	
Piledrivermen	10.43	.50	.50	.07	
Zone 5 - Kenosha County					
Carpenters	10.30	.40	.85		.05
Piledrivermen	10.38	.40	.85		.05
Zone 10 - Racine County					
Carpenters	10.10	.60	.85		.05
Piledrivermen	10.18	.60	.85		.05
Zone 11 - Sheboygan County					
Carpenters	9.35	.75	.30		
Piledrivermen	10.39	.75	.30		

MODIFICATIONS P. 13

DECISION NO. WI77-2102 Continued	Basic Hourly Rates	Fringe Benefits Payments H & W	Pensions	Vacation	Education and/or Appr. Tr.
Zone 13 - Walworth County					
Carpenters	10.28	.50	.50		.07
Piledrivermen	10.43	.50	.50		.07
Cement Masons.					
Zone 2 - Barron, Burnett, Chippewa, Dunn, Polk, Rusk, St. Croix, Sawyer and Washburn Counties	9.75	.65	.25		.05
Zone 3 - Adams, Clark, Forest, Langlade, Lincoln, Marathon, Menominee, Oneida, Portage, Price, Taylor, Vilas, and Wood Counties	8.80	.65	.30		.04
Zone 4 - Buffalo, Eau Clair, Pepin and Pierce Counties	9.75	.65	.25		.05
Zone 11 - Columbia and Sauk Counties	9.85	.65	.40		
Zone 14 - Grant County	9.93				
Zone 15 - Walworth County	9.26	.60	.60	.50	.05
Electricians:					
Zone 2 - Barron, Buffalo, Chippewa, Clark, Dunn, Eau Claire, Pepin, Pierce, Polk, Price, Rusk, St. Croix and Taylor Counties	10.92	5%	3%		
Zone 3 - Brown, Door, Kewaunee, and Shawano Count-ties	10.93	.60	3%		1/8%
Zone 4 - Florence Forest Counties	11.06	.40	3%		.5%
Zone 5 - Kenosha County	12.07	.51	3%	.25	.75%
Zone 6 - Crawford, Grant, Jackson, Juneau, La Crosse, Monroe, Richland, Trempealeau and Vernon counties	10.92	.55	3%		
Zone 7 - Walworth County	10.70	.45	3%	7%	½%
Zone 8 - Columbia, Dane, Dodge, Green Lake, Iowa, Marquette, and Sauk Counties	10.45	.74	3%	8%	

MODIFICATIONS P. 14

DECISION NO. WI77-2102 - MOD. #3	Basic Hourly Rates	Fringe Benefits Payments H & W	Pensions	Vacation	Education and/or Appr. Tr.
Electricians (cont'd)					
Zone 9 - Sheboygan County	9.83	.92	3%+.35	10%	½%
Zone 13 - Fond Dul Lac County	9.83	.92	3%+.35	10%	½%
Ironworkers:					
Zone 3 - Adams, Columbia, Crawford, Dane, dodge, Grant, Green Lake and Other Counties	10.72	.65	.375		.055
Zone 5 - Rock County	12.60	.65	.375		.10
Line Construction:					
Linemen	9.97	5%	7%		.5%
Heavy Equipment Operator	8.97	5%	7%		.5%
Light Equipment Operator	7.98	5%	7%		.5%
Heavy Groundman - Truck driver	6.98	5%	7%		.5%
Light Groundman - Truck driver	6.48	5%	7%		.5%
Groundman	5.48	5%	7%		.5%
Painters:					
Zone 3 - Brown, Door, Kewaunee, & Oconto Counties					
Brush	8.70	.80			
Spray	9.08	.80			
Zone 5 - Kenosha County					
Brush	9.325	.40	.40		
Spray	10.07	.40	.40		
Zone 6 - Adams, Clark, Crawford, Jackson, Juneau, La Crosse, Monroe, Portage, Vernon & wood Counties					
Brush	8.43		.45		
Spray	9.12		.45		
Zone 7 - Walworth County					
Brush	9.325	.40	.40		
Spray	10.07	.40	.40		
Zone 9 - Calumet and Mantitowoc Counties					
Brush	8.25				
Spray	8.75				
Zone 12 - Fond Du Lac, Green Lake, Marquette, Outagamie, Shawano, Waushara, Waupaca, and Winnebago Counties					
Brush and Steel	8.80	.70	.10		.03
Spray	9.30	.70	.10		.03
Zone 13 - Racine County					
Brush	9.20	.55	.60		.05
Spray	9.95	.55	.60		.05
Zone 15 - Ashland, Bayfield, Douglas, Iron, and Vilas Counties					
Brush	10.08	.40	.40		.09
Spray and Steel	10.68	.40	.40		.09

DECISION NO. WI77-2126 - MOD. #1 (42 FR 43364 - August 26, 1977) Statewide, Wisconsin	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Change:					
Carpenters:					
Zone 1 - Ashland, and Iron Counties and east ½ of Bayfield County					
Carpenters	$ 8.59	.50	.30	.15	
Piledrivermen	8.79	.50	.30	.15	
Cement Masons:					
Zone 4 - Eau Claire, Pepin, & Pierce Counties & the North ½ of Buffalo, Jackson & Trempealeau Counties	9.75	.65	.25		.05
Zone 10 - Columbia and Sauk Counties	9.85	.65	.40		
Zone 13 - Grant County	9.93				
Electricians:					
Zone 2 - Barron, Chippewa, Clark, Dunn, Eau Claire, Pepin, Pierce, Polk, Rusk and Taylor Counties etc.	10.92	5%	3%		½ of 1%
Zone 4 - Florence & Forest Cos. and that portion of Marinette County North of Ambest, Athelstone, and silver Cliff Townships	11.06	.40	3%		½ of 1%
Zone 5 - Kenosha County	12.07	.51	3%		.75%
Zone 6 - Crawford, Grant, Juneau, La Crosse, Monroe, Richland & Vernon Counties & the remainder of Buffalo, Jackson & Trempealeau Cos.	10.92	.55	3%		
Zone 8 - Columbia, Dane, Dodge Iowa & Sauk Counties and the remaidner of Green Lake and Marquette Counties	10.45	.74	3%	8%	.75%
Zone 9 - Sheboygan County	9.83	.92	3%+.35	10%	1½ of 1%
Zone 13 - Fond Du Lac County	9.83	.92	3%+.35	10%	1½ of 1%

DECISION NO. WI77-2126 continued	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Ironworkers:					
Zone 3 - Adams, Columbia, Crawford, Dane, Grant, Green Lake, Iowa, etc.	10.72	.65	.375		.055
Line Construction:					
Linemen	9.97	5%	7%		.5%
Heavy equipment Operator	8.97	5%	7%		.5%
Equipment Operator	7.98	5%	7%		.5%
Heavy Groundman - Truck driver	6.98	5%	7%		.5%
Light Groundman - Truck driver	6.48	5%	7%		.5%
Painters:					
Zone 3 - Brown, Door, Kewaunee, & Oconto Counties					
Brush	8.70	.80		.50	
Spray	9.08	.80		.50	
Zone 5 - Kenosha County					
Brush	9.325	.40	.40		
Steel	9.475	.40	.40		
Spray	10.07	.40	.40		
Zone 7 - Walworth County					
Brush	9.325	.40	.40		
Steel	9.475	.40	.40		
Spray	10.07	.40	.40		
Zone 9 - Manitowoc County and the South ½ of Calumet County					
Brush	8.25				
Spray & Steel	8.75				
Zone 15 - Ashland, Bayfield, Douglas, Iron & Vilas Counties					
Brush	10.08	.40	.40		.09
Spray & Steel	10.68	.40	.40		.09
Truck Drivers:					
Change Pensions on all Zones and all Groups to			$25.00a		

FOOTNOTE:

a. Per week per employee on payroll 30 days or longer.

SUPERSEDEAS DECISION

STATE: Texas

COUNTIES: Armstrong, Carson, Castro, Childress, Collingsworth, Dallam, Deaf Smith, Donley, Gray, Hansford, Hartley, Hemphill, Hutchinson, Lipscomb, Moore, Ochiltree, Oldham, Potter, Randall, Roberts, Sherman, Swisher & Wheeler

DECISION NO.: TX78-4002

DATE: Date of Publication

Supersedes Decision No. TX77-4253, dated September 30, 1977, in 42 FR 53149.

DESCRIPTION OF WORK: Residential construction consisting of single family homes and garden type apartments up to and including 4 stories.

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
BOILERMAKERS	$10.00	.50	1.00		.02
BRICKLAYERS	10.05		.30		
CARPENTERS	9.54		.40		.01
CEMENT MASONS	8.30				
ELECTRICIANS	10.58	.60	3%		1/2%
LABORERS:					
Laborers	5.16	.53	.27		
Mason tenders	5.32	.53	.27		
PAINTERS	8.45		.40		
PLUMBERS	9.56	.45	.65	.60	
SHEET METAL WORKERS	6.70	.35	.55		.10

DECISION NO. TX78-4002

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INCIDENTAL PAVING & UTILITIES & SITE PREPARATION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Asphalt Heaterman	$ 3.70				
Asphalt Raker	4.10				
Batching Plant Scaleman	4.90				
Carpenter	4.70				
Carpenter Helper	4.00				
Concrete Finisher (Paving)	4.50				
Concrete Finisher Helper (Paving)	3.50				
Concrete Finisher (Structures)	4.75				
Concrete Finisher Helper (Structures)	4.00				
Form Builder (Structures)	4.75				
Form Builder Helper(Structures)	4.50				
Form Liner (Paving & Curb)	4.00				
Form Setter (Paving & Curb)	4.00				
Form Setter Helper (Paving & Curb)	3.50				
Form Setter (Structures)	5.05				
Form Setter Helper (Structures)	4.40				
Laborer, Common	3.00				
Laborer, Utility Man	3.65				
Manhole Builder, Brick	4.00				
Mechanic	5.10				
Mechanic Helper	3.50				
Oiler	4.20				
Serviceman	4.05				
Painter (Structures)	5.00				
Pipelayer	3.75				
Pipelayer Helper	3.25				
Powderman	4.20				
Reinforcing Steel Setter(Paving)	4.35				
Reinforcing Steel Setter (Structures)	4.85				
Reinforcing Steel Setter Helper	3.65				
Sign Erector	3.50				
Spreader Box Man	4.35				
Swamper	3.10				
Power Equipment Operators:					
Asphalt Distributor	4.65				
Asphalt Paving Machine	5.00				
Broom or Sweeper Operator	3.55				
Bulldozer, 150 HP and Less	4.20				
Bulldozer, over 150 HP	4.85				
Concrete Paving Curing Machine	4.75				
Concrete Paving Finishing Machine	4.80				
Concrete Paving Form Grader	3.75				
Concrete Paving Mixer	4.80				
Concrete Paving Saw	4.30				
Crane, Clamshell, Backhoe, Derrick, Dragline, Shovel (less than 1½ CY)	4.55				

DECISION NO. TX78-4002

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INCIDENTAL PAVING & UTILITIES & SITE PREPARATION	Basic Hourly Rates	Fringe Benefits Payments: H & W	Pensions	Vacation	Education and/or Appr. Tr.
Power Equipment Operators (Cont'd):					
Crane, Clamshell, Backhoe, Derrick, Dragline, Shovel (1½ CY and Over)	$ 5.05				
Crusher or Screening Plant Op.	4.95				
Foundation Drill Operator (Crawler Mounted)	5.35				
Foundation Drill Operator (Truck Mounted)	5.85				
Foundation Drill Op. Helper	4.00				
Front End Loader (2½ CY & Less)	4.20				
Front End Loader (Over 2½ CY)	4.90				
Mixer (Over 16 CF)	4.65				
Motor Grader Op., Fine Grade	5.50				
Motor Grader Operator	5.00				
Roller, Steel Wheel (Plant-Mix Pavements)	3.50				
Roller, Steel Wheel (Other-Flat Wheel or Tamping)	3.90				
Roller, Pneumatic (Self-Propelled)	3.85				
Scrapers (17 CY and Less)	4.35				
Scrapers (Over 17 CY)	4.80				
Side Boom	4.00				
Tractor (Crawler Type) 150 HP and Less	3.80				
Tractor (Crawler Type) over 150 HP	4.30				
Tractor (Pneumatic) 80 HP and Less	3.75				
Tractor (Pneumatic) over 80 HP	4.30				
Traveling Mixer	4.35				
Trenching Machine, Light	4.00				
Trenching Machine, Heavy	4.00				
Wagon Drill, Boring Machine or Post Hole Driller Operator	4.00				
Truck Drivers:					
Single Axle, Light	3.00				
Single Axle, Heavy	3.75				
Tandem Axle or Semitrailer	3.45				
Lowboy-Float	3.55				
Transit-Mix	3.50				
Vibrator Man (Hand Type)	3.05				
Weighman (Truck Scales)	3.25				
Welder	5.50				

SUPERSEDEAS DECISION

STATE: Texas

COUNTIES: Bell, Bosque, Coryell, Falls, Hill & McLennan

DECISION NO.: TX78-4003

DATE: Date of Publication

Supersedes Decision No. TX77-4222, dated September 23, 1977, in 42 FR 48725.

DESCRIPTION OF WORK: Building Construction (does not include single family homes & garden type apartments up to & including 4 stories). (See current heavy & highway general wage determination for Paving & Utilities Incidental to Building Construction in Bosque, Falls, Hill & McLennan Counties).

BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments: H & W	Pensions	Vacation	Education and/or Appr. Tr.
ASBESTOS WORKERS:					
ZONE 1 - Bell, Coryell & Falls	$10.35	.60	.60		.08
ZONE 2 - Bosque, Hill & McLennan	10.03	.40	.76		.025
BOILERMAKERS	10.00	.50	1.00		.02
BRICKLAYERS	9.60		.55		.03
CARPENTERS:					
ZONE 1 - Bell & Coryell Cos.:					
Carpenters	8.70				
Millwrights	8.95				
ZONE 2 - Bosque, Falls, Hill & McLennan:					
Carpenters	8.95				
Millwrights	9.35				
CEMENT MASONS	8.69	.40	.30		
ELECTRICIANS:					
ZONE 1 - Bell (that part which is nearer to Waco than Austin but excluding that part of Ft. Hood, the boundary which presently is located approx. 2 miles inside the Bell Co. line & the City of Killeen), Bosque, Coryell (except that part of Ft. Hood south of Cowhouse Creek), Falls, Hill & McLennan Cos.	9.40	.60	3%		1/4%
ZONE 2 - Bell (that part which is nearer to Austin than Waco & not to extend more than 2 miles into Bell Co. from the southeast boundary line of Coryell Co., Gray Field & the City of Killeen) & Coryell (that part south of Cowhouse Creek) Counties	10.70		8%		.8%
ELEVATOR CONSTRUCTORS:					
Mechanics	9.91	.745	.35	4%+a+b	.02
Helpers	70%JR	.745	.35	4%+a+b	.02
Helpers (Probationary)	50%JR				
GLAZIERS	7.00				
IRONWORKERS	9.45	.55	1.00		.12
LABORERS:					
Unskilled	2.97				
Mason tenders & mortar mixers	3.55				
LATHERS	9.30			.80	.05
LINE CONSTRUCTION:					
Linemen; Linemen operators	11.52		3%		1/2%
Cable splicers	12.67		3%		1/2%
Groundman, 1st 6 months	6.91		3%		1/2%
Groundman, 2nd 6 months	7.49		3%		1/2%
Groundman, 1 year & over	8.06		3%		1/2%
PAINTERS:					
GROUP 1 - Brush	7.60				.04
GROUP 2 - Boiler pipes & steel, structural steel, windos jacks, roofs, stage work, smoke stack, water towers, boatswain chair	8.10				.04

DECISION NO. TX78-4003

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BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments H & W	Pensions	Vacation	Education and/or Appr. Tr.
GROUP 3 - Ames tools for dry wall	$ 8.20				.04
GROUP 4 - Spray work & self feeding rollers	8.35				.04
GROUP 5 - Steam cleaning, sandblasting & hazardous work	8.70				.04
PLASTERERS	9.54	.45	.50		.01
PLUMBERS & PIPEFITTERS:					
ZONE 1 - Area within a 35 mile radius of Waco including Temple, Marline, Clifton & Hillsboro	8.70	.30	.33		.03
ZONE 2 - All other areas	9.10	.30	.33		.03
ROOFERS:					
GROUP 1 - Slate, tile, asbestos, roofing & siding	6.95				.03
GROUP 2 - Composition, built-up, damp & waterproofing	6.80				.03
GROUP 3 - Kettlemen	5.10				.03
SHEET METAL WORKERS:					
ZONE 1 - Within a radius of 20 miles from the McLennan Co. Court House, Waco	9.26		.39		.05
ZONE 2 - Over 20 miles but less than 45 miles including the towns of Hillsboro, Temple, Marlin, Gatesville & Clifton	9.76		.39		.05
ZONE 3 - Over 45 miles	10.26		.39		.05
SPRINKLER FITTERS	11.15	.65	.95		.08
TRUCK DRIVERS	2.80				
WELDERS - receive rate prescribed for craft performing operation to which welding is incidental.					

FOOTNOTES FOR ELEVATOR CONSTRUCTORS:

a - 1st 6 mos. - none; 6 mos. to 5 yrs. - 2%; over 5 yrs. - 4% of basic hourly rate

b - Paid Holidays A thru G

PAID HOLIDAYS FOR ELEVATOR CONSTRUCTORS:
A-New Years' Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-the Friday after Thanksgiving Day; F-Christmas Day

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BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments H & W	Pensions	Vacation	Education and/or Appr. Tr.
POWER EQUIPMENT OPERATORS					
GROUP 1	$ 8.63		.40		
GROUP 2	7.56		.40		
GROUP 3	6.34		.40		
GROUP 4	6.23		.40		

POWER EQUIPMENT OPERATORS CLASSIFICATION DEFINITIONS

GROUP 1 - Heavy Duty Mechanic; Blade Grader - Self-propelled; Bull Clam; Back Filler; Derricks, power operated (all types); Dragline; Push Cat Operator; Euclid Operator; Bull Dozer and all types of Cat Tractors; Cable-Way; Back Hoe; Crane, Power Operated (all types); Elevating Grader, self-propelled; Hoist, Motor-Driver, two drums or more; Mix Mobile; High-Lifts & Loaders, over 1/3 cu. yd. capacity; Winch Truck; Locomotive; Mixer, 14 cu. ft. or over; Paving Mixer (all sizes); Scraper; Trenching Machine (all sizes); Gradall; Foundation Boring Machine; Scoopmobile; Shovel, power operated; Pump Crete Machines; Clam Shell Operator; Rock Crusher Operated on Job; Welding Machine, 6 to 12; Two 125 cu. ft. Compressors; Well points, including installations

GROUP 2 - Blade Grader, Towed; Flex Plane; Form Grader; Mixer, less than 14 cu. ft.; Pulsometer; Truck Crane Driver & Oiler, Combination man; Gasoline or Diesel Driven Welding Machine, 3 to 6; Hoist, Single Drum; Pump, 2½ in. or larger; Pneumatic Roller; High-Lifts & Loaders, 1/3 cu. yd. or less; Forklift, 1500 lbs. capacity or less; Air Compressors, anytime there are two or more attachments operating on a 125 cu. ft. compressor, a light equipment operator shall be employed. One 125 cu. ft. air compressor and one welding machine requires no operator. One 125 cu. ft. compressor and two welding machines or any 2 air compressors equivalent to a 125 cu. ft. air compressor requires a light equipment operator

GROUP 3 - Fireman

GROUP 4 - Oiler

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INCIDENTAL PAVING & UTILITIES (BELL & CORYELL COUNTIES)	Basic Hourly Rates	Fringe Benefits Payments H & W	Pensions	Vacation	Education and/or Appr. Tr.
Air Tool Man	$ 3.00				
Asphalt Heaterman	3.55				
Asphalt Raker	4.00				
Batching Plant Scaleman	4.25				
Carpenter	4.35				
Carpenter Helper	3.55				
Concrete Finisher (Paving)	4.75				
Concrete Finisher Helper(Paving)	3.75				
Concrete Finisher (Structures)	4.50				
Concrete Finisher Helper (Structures)	3.50				
Concrete Rubber	3.35				
Electrician	6.50				
Electrician Helper	4.00				
Form Builder (Structures)	4.00				
Form Builder Helper(Structures)	3.50				
Form Setter (Paving & Curb)	4.20				
Form Setter (Structures)	4.25				
Form Setter Helper (Structures)	3.55				
Laborer, Common	3.00				
Laborer, Utility Man	3.00				
Mechanic	4.60				
Mechanic Helper	3.80				
Oiler	3.25				
Serviceman	3.50				
Painter (Structures)	3.50				
Piledrivermen	4.00				
Pipelayer (Concrete & Clay)	4.00				
Pipelayer Helper (Concrete & Clay)	3.00				
Plumbers:					
Zone 1 - 35 miles from Waco, Texas including town of Temple	8.70	.30	.33		.03
Zone 2 - all area not included in Zone 1	9.10	.30	.33		.03
Powderman	4.35				
Reinforcing Steel Setter (Structures)	4.50				
Reinforcing Steel Setter Helper	3.00				
Sign Erector	4.50				
Sign Erector Helper	3.00				
Spreader Box Man	4.10				
Swamper	4.05				
Power Equipment Operators:					
Asphalt Distributor	4.00				
Asphalt Paving Machine	4.10				
Broom or Sweeper Operator	3.90				
Bulldozer, 150 HP and Less	3.75				
Bulldozer, over 150 HP	4.50				
Concrete Paving Curing Machine	4.00				
Concrete Paving Saw	4.75				
Crane, Clamshell, Backhoe, Derrick, Dragline, Shovel (less than 1½ CY)	4.00				

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INCIDENTAL PAVING & UTILITIES (BELL & CORYELL COUNTIES)	Basic Hourly Rates	Fringe Benefits Payments H & W	Pensions	Vacation	Education and/or Appr. Tr.
Power Equipment Operators (Cont'd):					
Crane, Clamshell, Backhoe, Derrick, Dragline, Shovel (1½ CY and Over)	$ 4.75				
Crusher or Screening Plant Op.	4.15				
Foundation Drill Operator (Truck Mounted)	5.40				
Foundation Drill Operator Helper	4.25				
Front End Loader (2½ CY & Less)	4.00				
Front End Loader (Over 2½ CY)	4.40				
Motor Grader Op., Fine Grade	5.00				
Motor Grader Operator	4.50				
Roller, Steel Wheel (Plant-Mix Pavements)	3.85				
Roller, Steel Wheel (Other-Flat Wheel or Tamping)	3.65				
Roller, Pneumatic (Self-Propelled)	3.40				
Scrapers (17 CY and Less)	3.75				
Scrapers (Over 17 CY)	4.00				
Tractor (Crawler Type) 150 HP and Less	3.35				
Tractor (Crawler Type) over 150 HP	3.75				
Tractor (Pneumatic) 80 HP & Less	3.40				
Tractor (Pneumatic) over 80 HP	4.00				
Traveling Mixer	4.25				
Trenching Machine, Light	4.00				
Trenching Machine, Heavy	4.45				
Wagon Drill, Boring Machine or Post Hole Driller Operator	3.80				
Truck Drivers:					
Single Axle, Light	3.45				
Tandem Axle or Semitrailer	3.55				
Lowboy-Float	4.15				
Welder	4.50				
Welder Helper	3.25				

SUPERSEDEAS DECISION

STATE: Texas COUNTY: Howard
DECISION NO.: TX78-4004 DATE: Date of Publication
Supersedes Decision No. TX77-4201, dated August 19, 1977, in 42 FR 42136.
DESCRIPTION OF WORK: Building (including Residential) Construction. (See current heavy & highway general wage determination for Paving & Utilities Incidental to Building Construction).

	Basic Hourly Rates	Fringe Benefits Payments H & W	Pensions	Vacation	Education and/or Appr. Tr.
BRICKLAYERS	$ 7.00				
CARPENTERS	6.10				
CEMENT MASONS	5.00				
ELECTRICIANS	7.40	.30	1%		1/10%
IRONWORKERS, STRUCTURAL & ORNAMENTAL	8.83	.55	1.00		.10
LABORERS:					
Laborers	3.06				
Mason tenders	3.50				
PAINTERS	4.50				
PLUMBERS	4.26				
ROOFERS	4.00				
SHEET METAL WORKERS	5.25				
TILE SETTERS	4.00				
TRUCK DRIVERS	2.65				
WELDERS - receive rate prescribed for craft performing operation to which welding is incidental.					

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INCIDENTAL PAVING & UTILITIES & SITE PREPARATION (RESIDENTIAL CONSTRUCTION ONLY)	Basic Hourly Rates	Fringe Benefits Payments H & W	Pensions	Vacation	Education and/or Appr. Tr.
Air Tool Man	$ 3.00				
Asphalt Heaterman	3.25				
Asphalt Raker	3.90				
Asphalt Shoveler	3.50				
Batching Plant Scaleman	4.25				
Batterboard Setter	3.65				
Carpenter	4.40				
Carpenter Helper	3.30				
Concrete Finisher (Paving)	4.50				
Concrete Finisher Helper(Paving)	3.25				
Concrete Finisher (Structures)	4.40				
Concrete Finisher Helper (Structures)	3.50				
Electrician	6.30				
Form Builder (Structures)	4.50				
Form Builder Helper (Structures)	3.15				
Form Setter (Paving & Curb)	4.65				
Form Setter Helper (Paving & Curb)	4.00				
Form Setter (Structures)	4.75				
Form Setter Helper (Structures)	3.70				
Laborer, Common	3.00				
Laborer, Utility Man	3.50				
Manhole Builder, Brick	3.00				
Mechanic	4.00				
Mechanic Helper	3.75				
Oiler	3.50				
Serviceman	3.50				
Painter (Structures)	3.50				
Pipelayer	3.60				
Pipelayer Helper	3.50				
Powderman	4.00				
Powderman Helper	3.10				
Reinforcing Steel Setter (Structures)	3.75				
Reinforcing Steel Setter Helper	3.25				
Steel Worker (Structural)	3.75				
Sign Erector	4.15				
Sign Erector Helper	3.25				
Spreader Box Man	3.85				
Power Equipment Operators:					
Asphalt Distributor	4.10				
Asphalt Paving Machine	4.00				
Broom or Sweeper Operator	4.00				
Bulldozer, 150 HP and Less	4.00				
Bulldozer, over 150 HP	4.50				
Concrete Paving Saw	4.50				
Crane, Clamshell, Backhoe, Derrick, Dragline, Shovel (less than 1½ CY)	4.25				
Crane, Clamshell, Backhoe, Derrick, Dragline, Shovel (1½ CY and Over)	5.00				

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INCIDENTAL PAVING & UTILITIES & SITE PREPARATION (RESIDENTIAL CONSTRUCTION ONLY)	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Power Equipment Operators (Cont'd):					
Crusher or Screening Plant Op.	$ 4.05				
Elevating Grader	4.10				
Foundation Drill Operator (Crawler Mounted)	4.60				
Foundation Drill Operator (Truck Mounted)	5.50				
Front End Loader (2½ CY & Less)	3.75				
Front End Loader (Over 2½ CY)	4.45				
Motor Grader Op., Fine Grade	5.00				
Motor Grader Operator	4.40				
Roller, Steel Wheel (Plant-Mix Pavements)	3.50				
Roller, Steel Wheel (Other-Flat Wheel or Tamping)	3.45				
Roller, Pneumatic (Self-Propelled)	3.75				
Scrapers (17 CY and Less)	3.70				
Scrapers (Over 17 CY)	4.00				
Self-Propelled Hammer	3.50				
Side Boom	3.50				
Tractor (Crawler Type) 150 HP and Less	3.45				
Tractor (Crawler Type) over 150 HP	3.85				
Tractor (Pneumatic) 80 HP & Less	3.25				
Tractor (Pneumatic) over 80 HP	3.75				
Traveling Mixer	3.00				
Trenching Machine, Light	4.05				
Wagon Drill, Boring Machine or Post Hole Driller Operator	3.50				
Truck Drivers:					
Single Axle, Light	3.25				
Single Axle, Heavy	3.25				
Tandem Axle or Semitrailer	3.40				
Lowboy-Float	3.95				
Winch	3.50				
Weighman (Truck Scales)	3.50				
Welder	4.00				

[FR Doc. 78-732 Filed 1-12-78; 8:45 am]

federal register

FRIDAY, JANUARY 13, 1978
PART V

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of the Secretary

■

IMPLEMENTATION OF EXECUTIVE ORDER 11914

Nondiscrimination on the Basis of Handicap in Federally Assisted Programs

[4110-12]

Title 45—Public Welfare

SUBTITLE A—DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, GENERAL ADMINISTRATION

PART 85—IMPLEMENTATION OF EXECUTIVE ORDER 11914, NONDISCRIMINATION ON THE BASIS OF HANDICAP IN FEDERALLY ASSISTED PROGRAMS

Coordination of Federal Agency Enforcement of Section 504 of the Rehabilitation Act of 1973

AGENCY: Department of Health, Education, and Welfare.

ACTION: Final rule.

SUMMARY: This rule implements Executive Order 11914, "Nondiscrimination With Respect to the Handicapped in Federally Assisted Programs," under which the Department of Health, Education, and Welfare is required to coordinate governmentwide enforcement of section 504 of the Rehabilitation Act of 1973, as amended. In particular, the rule sets forth enforcement procedures, standards for determining which persons are handicapped, and guidelines for determining what practices are discriminatory. These procedures, standards, and guidelines are to be followed by each federal agency that provides federal financial assistance in issuing regulations implementing section 504.

EFFECTIVE DATE: January 13, 1978.

FOR FURTHER INFORMATION, CONTACT:

Anne Beckman, Office for Civil Rights, Department of Health, Education, and Welfare, 330 Independence Avenue SW., Washington, D.C. 20201, 202-245-6118.

SUPPLEMENTARY INFORMATION:

BACKGROUND

As part of the Rehabilitation Act of 1973 (Pub. L. 93-112), Congress enacted section 504, which provides that "no otherwise qualified handicapped individual in the United States * * * shall, solely by reason of his handicap, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance." The definition of "handicapped individual" applicable to section 504 is contained in section 111(a) of the Rehabilitation Act Amendments of 1974 (Pub. L. 93-516).

On April 28, 1976, the President issued Executive Order 11914 (41 FR 17871) to provide for consistent governmentwide enforcement of section 504; the executive order is reprinted at Appendix A to this rule. The order directs the Secretary of Health, Education, and Welfare to coordinate the implementation of section 504 by all Federal departments and agencies that extend financial assistance to any program or activity. Specifically, section 1 directs the Secretary to establish standards for determining who are handicapped individuals and to establish guidelines for determining what are discriminatory practices under section 504 and to assist other agencies as necessary to assure the coordinated and consistent implementation of section 504. Sections 2 and 3 also contemplate that this Department will establish procedures to guide other Federal departments and agencies in implementing section 504.

In addition to setting forth the responsibilities of this Department, the executive order directs other agencies to issue regulations consistent with HEW standards and procedures, to furnish the Secretary with reports and information upon request, and to cooperate with this Department in their implementation of section 504.

Finally, the executive order, in section 3, contains general procedures and sanctions for securing compliance with section 504 and, in section 5, requires the consistent implementation of all of Title V of the Rehabilitation Act of 1973 as well as the Architectural Barriers Act of 1968 (Pub. L. 90-480).

On May 4, 1977, this Department issued its final regulation implementing section 504 as to recipients of financial assistance from HEW.

On June 24, 1977, the Department issued a proposed rule to carry out its responsibilities under the executive order by specifying procedures for the promulgation and enforcement of section 504 regulations by all agencies providing financial assistance, standards for determining who are handicapped individuals, and guidelines for determining what practices are discriminatory under section 504. Fifty comments were received during the 30-day public comment period. The Secretary's response to these comments and the explanation for changes in the proposed rule are set forth below in the summary of the final regulation.

SUMMARY OF RULE AND ANALYSIS OF COMMENTS

Subpart A of this regulation sets forth general definitions and uniform procedures for the enforcement of section 504.

Section 85.3(e) defines the term "federal financial assistance." Several commenters objected to the exclusion of contracts of insurance and guaranty from that definition because programs whose only federal assistance is in the form of federal loan guarantees, such as the Federal Deposit Insurance Corporation (FDIC) and Federal Housing Administration (FHA) programs, are thereby exempt from coverage. In light of this concern, the Department asked the Department of Justice for an opinion as to whether contracts of insurance and guaranty are covered by section 504. The Department of Justice has advised this Department, on the basis of its analysis of the legislative history of section 504, that Congress intended the reach of section 504 to be "co-extensive with that of (titles VI and IX), thus excluding programs of guarantee and insurance." The final regulation reflects that determination.

Despite some difference in the wording of the definitions of federal financial assistance in the regulations implementing section 504 and title VI, the substance of the two definitions does not differ. Several commenters misunderstood the exclusion of "ultimate beneficiaries" in § 85.3(d); an ultimate beneficiary is not the final "recipient," but the student, patient, or other individual who participates in the assisted program.

One comment asked whether the definition of facility in § 85.3(f) applies only to land-based facilities. Although the definition is not so limited, the Department agrees with the observation that different standards may be needed for vessels than for other facilities. The appropriate mechanism for the recognition of such differences, however, is in the regulations of the agencies that provide assistance to programs involving vessels.

Section 85.4 contains procedures for the promulgation of agency regulations. In accordance with section 2 of the executive order, such regulations are required to be consistent with the standards and guidelines contained in this regulation. Agencies are encouraged to examine Subparts A, B, and C of the HEW section 504 regulation to determine whether their regulations should include any of the more detailed provisions to be found there. In addition, each agency should examine the programs and activities to which it provides assistance to determine whether detailed requirements concerning any such program or activity should be included in its regulation, similar to those contained in Subparts D, E, and F of the HEW section 504 regulation.

A number of recipients objected to the requirement in paragraph (a) that each agency issue a separate section 504 regulation and would have preferred implementation through one regulation enforced by one agency—the system used for section 503. Although the provision for interagency cooperation set forth in § 85.6 should take care of many of the problems foreseen by these commenters, there are admitted advantages to the single agency system. This approach is precluded here, however, because section

504, unlike section 503, does not place rulemaking authority in a single agency and the executive order itself directs each federal agency to issue its own regulation. Furthermore, because section 504 covers the provision of services as well as employment, it does not lend itself as readily to a single regulation as does section 503: While employment presents fairly uniform issues from agency to agency, the problems that arise in various service programs differ widely.

Section 85.4(b) sets forth the schedule for issuing agency regulations. In response to comment, the time for preparation of a proposed rule has been extended to 90 days. Three agencies commented that more than 90 days would be required for this purpose. While the Department recognizes that the problems to be resolved by these agencies are complex, it believes that every effort should be made to meet this schedule.

As stated in the proposed regulation, the Secretary believes that the provision for review of each agency's draft final regulation by the Director of the HEW Office for Civil Rights before it is finally issued is an effective and appropriate method of promoting consistency of regulation under section 504 throughout the government. Although a few commenters suggested the need for some additional, formal mechanism for determining whether an agency regulation conforms to this regulation, we believe that public comment, together with review by the Office for Civil Rights, will suffice.

One change has been made in paragraph 4(c). The phrase "aid, benefits, or services" has been substituted for the word "services" so as to describe more adequately the nonemployment elements of various assisted programs and activities.

One comment requested a statement by the Department that this regulation creates no judicially enforceable rights. Such a statement, we believe, is inappropriate and unnecessary. Whether any legally enforceable rights are created by this regulation is a matter for courts to decide. We would only observe that the regulation applies to Federal agencies, not to recipients, and that it has no retroactive reach.

Comments led to three changes in section 85.5 (Enforcement). Adoption of title VI enforcement procedures is not a required element of the enforcement system; even those commenters who do not entirely support the title VI procedures favored their inclusion because of the advantages of a single complaint mechanism. The language of the consultation requirement has been made consistent with the corresponding language of the HEW section 504 regulation. A requirement that recipients conduct self-evaluations has also been added because of the benefits to be gained by agencies, recipients, and handicapped persons of a mechanism for effecting compliance without Federal intervention. More specific guidance for conducting an evaluation, as well as a specific time for its completion, should be provided in each agency's regulation.

Despite these additions, § 85.5 is still not intended to be exhaustive. Agencies may wish to consider other additions from the HEW section 504 regulation, such as the designation by a recipient of an employee to coordinate 504 enforcement. Although § 85.5 has not been amended to require agencies to conduct pre-grant compliance reviews, as suggested, the Department does agree that they are an effective means of ensuring compliance and therefore encourages agencies to conduct such reviews as a routine matter, especially with respect to major grants.

Section 85.6 contains provisions concerning interagency cooperation. Although commenters were pleased that the issue of coordination of enforcement among the various Federal agencies had been addressed, many felt that this section failed to resolve adequately problems of the recipient who receives grants from more than one agency: Multiple assurance forms, inconsistent regulations or enforcement procedures, multiple investigations. Several commenters also suggested that the final regulation incorporate some method for determining the primary enforcement agency (such as the agency that provides the largest grants). While the Department is sympathetic with recipients' concerns, it believes that these problems can be resolved by the agencies themselves without further regulation. As noted in the proposed regulation, agencies are encouraged to extend existing title VI delegations to section 504. Ensuring consistent regulations should alleviate the problem as well. If, however, these mechanisms prove to be inadequate, the Department will issue further rules on the subject.

One comment suggested the need for standardized referral procedures when complainants appeal to the wrong agency. Although no change has been made in the regulation, the Department feels the issue is an important one. Each agency should adopt internal procedures to ensure that misdirected complaints are referred to the proper agency, rather than being returned to complainants, and to ensure that complainants are promptly notified of the referral.

Section 85.7 contains provisions for coordination with sections 502 and 503 of the Rehabilitation Act; two minor clarifying changes have been made.

One commenter inquired as to the precise meaning of "consult" and "coordinate" as used in this section. The terms are not meant to specify any explicit procedures. The requirement for consultation with the Architectural and Transportation Barriers Compliance Board (ATBCB) in developing requirements for the accessibility of new construction and alteration is based simply on the Department's belief that agencies should take advantage of the Board's expertise in this area.

The coordination requirement is designed to avoid inconsistent or duplicative enforcement where the jurisdiction of sections 502 or 503 overlaps with that of section 504. The ATBCB itself suggested that each agency be required to enter into a memorandum of understanding with the Board. Requiring formal agreements for this purpose, we believe, is neither necessary nor advisable.

Two agencies suggested that all matters of employment discrimination against handicapped persons be coordinated by the Department of Labor (DOL) to avoid inconsistent requirements being imposed upon entities that are both federal recipients and federal contractors. We believe that the requirements of the two regulations are not inconsistent despite some variance in language. There must, of course, be close coordination of enforcement with DOL when a recipient is also a contractor. A general rule that DOL should be the primary enforcement agency in this situation would not, however, be appropriate. Where a corporation that is a federal contractor gets minimal assistance from another agency, DOL would be the natural lead agency. But where, for example, a university with a major HEW grant is also a federal contractor, HEW would more appropriately take the primary enforcement role, even with respect to employment.

Several suggestions were received concerning consultation and coordination with other agencies in areas of potential overlap. The Department is reluctant to build in any more of these requirements. The opportunity that each agency will have to comment on the regulation proposed by each of the other agencies should suffice to handle any other similar situations.

As noted in the proposal, the Department will, on a continuing basis, fulfill its responsibilities under the executive order to assist and consult with other agencies in their implementation of section 504 and to monitor compliance with the executive order.

Subpart B of this regulation contains the standards for determining who are "handicapped persons" and "qualified handicapped persons" within the meaning of section 504. Except for the addition noted below, the definition of handicapped person (§ 85.31) is identical to the one contained in § 84.3(j) of HEW's section 504 regulation. Further discussion of its provisions may be found in paragraph 3 of Appendix A of that regulation (42 FR at 22685-6). A final sentence has been added to the definition listing, for illustrative purposes, some of the diseases and impairments that are included in the term "physical or mental impairment." It should be noted that this definition of handicapped person does not supersede or interfere with the narrower definitions of the term established by statute for specific purposes, such as reduced transportation fares or eligibility for vocational rehabilitaion services. Agencies using such definitions may not, however, substitute them for the definition prescribe in this regulation in connection with their implementation of section 504.

It is again noted that drug addiction and alcoholism are included in the list of diseases and impairments. As stated in the proposal, the question of section 504's application to drug addicts and alcoholics was a difficult one on which the Secretary of HEW sought the advice of the Attorney General. In an opinion dated April 12, 1977, the Attorney General concluded that drug addiction and alcoholism are physical or mental impairments and are thus handicaps for the purpose of section 540 if they result in a substantial limitation of a "major life activity."

A detailed analysis of the implications of the inclusion of drug addicts and alcoholics within the scope of section 504 is set forth in paragraph 4 of Appendix A of the HEW regulation (42 FR at 22686). In response to concern again expressed in a number of comments, we emphasize that the fact that drug addiction and alcoholism may be handicaps does not mean that the behavioral manifestations of these conditions must be ignored in determining whether a person is qualified for services or employment. The statute applies only to qualified handicapped persons.

The definition of qualified handicapped person in §85.32 has been adapted from §84.3(k) of the HEW section 504 regulation. Other agencies may wish to supplement its provisions with additional guidance concerning qualifications for specific programs, as was done in §84.3(k) (2) and (3) of the HEW section 504 regulation. Several comments objected to the difference in wording between §85.32(a) of this regulation and section 60-741.2 of the Department of Labor section 503 regulation. No difference in substance is thereby intended; this Department believes that its definition more adequately emphasizes the prohibition against deeming a handicapped person to be unqualified on the basis of functions that are not necessary to the successful performance of the job in question.

A number of comments from the transportation field raised the question of whether such factors as safety may be considered in determining whether a handicapped person, especially one who is or has been alcoholic or emotionally ill, is qualified for a job. The Secretary again wishes to reassure recipients that such considerations are appropriate and are not considered a violation of section 504, so long as they are based on facts relating to the individual applicant's qualifications, rather than on assumptions or stereotypes.

Subpart C of this regulation, sets forth guidelines for determining discriminatory practices; these are, in general, minimum requirements. Except where obvious discrepencies in implementation would result, other agencies may exceed these standards if they wish. The subpart is divided into three parts: General, based on §84.4 of the HEW section 504 regulation; Employment, based on Subpart B of the HEW section 504 regulation, and Program Accessibility, based on Subpart C of the HEW section 504 regulation. A more detailed discussion of these subparts than is contained below may be found in Appendix A of the HEW regulation.

The general prohibitions against discrimination on the basis of handicap set forth in §85.51 incorporate basic principles that the Department determined, in developing its own regulation, to be inherent in section 504. First, section 504, like other nondiscrimination statutes, prohibits not only those practices that are overtly discriminatory but also those that have the effect of discriminating. And it is equal opportunity, not merely equal treatment, that is essential to the elimination of discrimination on the basis of handicap. Thus, in some situations, identical treatment of handicapped and nonhandicapped persons is not only insufficient but is itself discriminatory. On the other hand, separate or different treatment can be permitted only where necessary to ensure equal opportunity and truly effective benefits and services. Federally assisted programs and activities must thus be provided in the most integrated setting appropriate to the needs of participating handicapped persons.

Several commenters asked about the effect of §85.51 on the previously issued regulation of the Department of Transportation (DOT) implementing the Urban Mass Transportation Act (UMT Act) with respect to handicapped persons. This Department has not reviewed the UMTA regulation because it was issued before the promulgation of these guidelines. In the course of developing its regulation to implement section 504, DOT will undoubtedly examine its prior regulations with a view toward incorporating or revising their underlying concepts in its 504 regulation. The DOT section 504 regulation will be subject to public comment and to reveiw by this Department.

Furthermore, the Department's interpretation of §85.51 on matters of physical accessibility is set forth in §§85.56-58; it is these sections that, in general, should be looked to for guidance on this subject. This observation is also relevant to the many questions raised by commenters concerning the application of various provisions of §85.51 to specific transportation situations. In response to comment, the Department wishes to make clear that it does not construe this section, nor §§85.56-58, to preclude in all circumstances the provision of specialized services as a substitute for, or supplement to, totally accessible services, nor do these sections require door-to-door transportation service. Neither does paragraph (b)(4) of this section require buses to move their regular route stops to the doors of handicapped riders.

Section 85.51 (b)(3) prohibits recipients from utilizing criteria or methods of administration that would have the effect of subjecting handicapped persons to discrimination on the basis of handicap. The main application of this provision is to state agencies that recieve federal funds and then distribute the funds to other entities. These state agencies are obligated to develop methods of administering the distribution of federal funds so as to ensure that handicapped persons are not subjected to discrimination on the basis of handicap either by the second-tier recipients or by the manner in which the funds are distributed. The prohibitions of this paragraph, as well as of paragraph (b)(1), apply not only to direct actions of a recipient but also to actions committed through contractual agreements or similar arrangements. This provision is based on the premise that a recipient should not be able to do indirectly that which it cannot do directly.

Sections 85.52-55 contain the basic requirements for the elimination of discrimination on the basis of handicap in employment. These sections should be augmented, where possible, with provisions appropriate to the programs assisted by each agency. Specifically, §85.53 could be supplemented, as is the corresponding §84.12 of the HEW section 504 regulation, with examples of actions constituting reasonable accommodation and with factors to be considered in determining undue hardship; and §85.54, with provisions adapted from the more specific requirements of the parallel §84.13 of the HEW section 504 regulation.

One comment raised an issue of interest to those agencies that decide to augment §85.53 with examples of reasonable accommodation. Because of the tendency of some readers to equate this requirement with physical accommodations, any list of examples should include other types of actions, such as job restructuring and modified work schedules.

One comment to § 85.52, raised in the context of the transportation industry but of general applicability, inquired about the effect of this section on local, state, and federal laws that govern, in the interest of safety, driver eligibility. Local and state laws affecting the eligibility of handicapped persons for employment may continue to be applied, but only if they set standards that are job related and that do not unjustifiably disqualify such persons for particular jobs. Federal regulations as well should be reviewed to determine whether they meet this standard.

In response to comment, a new paragraph (b), taken from the HEW section 504 regulation, has been added to this section. It is designed to emphasize the prohibition on such practices as classifying certain jobs as being for handicapped persons.

In § 85.54, the word "nonjob-related" has been deleted as redundant. A test or other selection criterion "discriminates" if it screens out or tends to screen out handicapped persons but is not job related.

Although § 85.55, like § 84.14 of the HEW section 504 regulation, generally bans preemployment medical examinations and inquiries concerning handicap, certain qualifications to this general prohibition, found in § 84.14 and cross-referenced in § 85.55, should be noted. First, while employers may not, during the application process, inquire about the existence of a specific handicap (for example, epilepsy), they may ask about the applicant's ability to perform duties necessary to the job in question. Second, they may make voluntary inquiries as to handicap if they are subject to remedial or affirmative action obligations or if they are undertaking voluntary action to increase their employment of handicapped persons. Third, they may condition an offer of employment on the successful completion of a medical examination: *Provided*, That the examination follows the requirements of § 84.14(c) and that no offer is withdrawn on the basis of medical conditions that are not job related.

Several comments objected to the difference between the positions taken in the section 503 regulation and § 85.55 of this regulation on the question of preemployment inquiries and medical examinations. As discussed above, § 85.55 requires physical examinations and inquiries as to handicap to be postponed until after the hiring decision (which, again, may be conditioned on the result of the examination), whereas the section 503 regulation allows such examinations and inquiries to be made before an offer of employment.

The issuance of the DOL section 503 regulation preceded that of the HEW section 504 regulation by several years. During that time, the Department received extensive comment on the need to limit inquiries as to handicap in order to reduce the potential for discrimination, especially with respect to persons with nonvisible handicaps. We believe that the standard outlined above, although different from that of the DOL section 503 regulation, is necessary to achieve that objective; one virtue of this standard is that it makes it possible to determine whether the reason for not hiring a handicapped person is because of handicap. We also believe that legitimate purposes for obtaining such information are fulfilled as well at this later stage in the hiring process.

The misunderstanding of this section apparent in many comments makes it important to emphasize again that this provision does not prohibit taking job-related conditions into account in making employment decisions, nor does it preclude a recipient from obtaining information as to such conditions. It merely affects the time at which and the manner in which the information may be obtained.

Sections 85.56-58 concern "program accessibility," a term that summarizes the concept of prohibiting the exclusion of handicapped persons from programs by virtue of architectural barriers to such facilities as buildings, vehicles, and walks, while not requiring that existing facilities be completely barrier-free. Although new facilities are to be designed and constructed so as to be physically accessible to handicapped persons, structural modifications of existing facilities need be undertaken only where other methods are inadequate to assure that a program is available to handicapped persons. This final regulation has been amended to take into account the special problems of making various modes of transportation "program accessible," and the Department recognizes that the implementation of the concept of program accessibility will necessarily vary in other programs. As stated in the proposal, however, the Department believes that the basic principles contained in §§ 85.56-58, as amended, are appropriate governmentwide and are essential to the effective and consistent implementation of section 504.

Section 85.56 establishes the general standard for nondiscriminatory physical access to federally assisted programs and activities under section 504. It does not prohibit architectural barriers; it does prohibit exclusion of handicapped people from federally assisted programs and activities by virtue of such barriers. Sections 85.57-8 describe the means by which this standard is to be reached.

Section 85.57 has been amended and divided into three paragraphs. A new sentence has been added to paragraph (a) to rectify the misunderstanding, evident in some comments, that each existing facility must be altered.

Agencies are urged to set forth in their regulations illustrative types of actions that recipients may use as alternatives to structural changes to existing facilities. If they do so, agencies should also include the requirement, intrinsic to section 504, that priority be given to methods that offer programs and activities to handicapped persons in the most integrated setting appropriate. (See § 84.22(b) of the HEW section 504 regulation.) Agencies may also wish to consider supplementing § 85.57 with other details from section 84.22 of the HEW section 504 regulation.

In response to comment, the Department wishes to make clear that § 85.57 does not preclude other agencies from allowing recipients to choose among appropriate alternative methods of achieving program accessibility, so long as the agency itself sets an acceptable standard for what constitutes program accessibility.

Several transportation comments proposed that the word "program," for purposes of program accessibility, be interpreted to mean the entire transportation system of a certain geographic area, as opposed to particular modes of transportation (bus, rail) in the area. The Department rejects this concept as a general matter.

We recognize, however, that there are special problems to achieving program accessibility with the three-year time period for certain modes of transportation. Paragraph (b) has, therefore, been amended to allow more than three years for compliance for any mode of transportation in which program accessibility can be achieved within that period only through extensive alterations entailing extraordinary costs. Such exceptions may be allowed only where alternate, accessible modes of transportation are available. The specific period of time for compliance is to be established by the federal agency administering the transportation program (the Department of Transportation, in practically all cases); it may vary from mode to mode. The Department believes that this departure from the general scheme is justified by the lack of acceptable alternatives to extremely expensive alterations in the provision of some transportation services.

The Department recognizes that special problems may also be encountered in achieving program accessibility in existing public housing projects within the three-year schedule. Because the program accessibility standard itself requires only that a small percentage of units be accessible (and that there be access to the project itself), the Department believes that the standard can be met within the prescribed schedule. We are prepared to consult with the Department of Housing and Urban Development as compliance progresses and will reexamine the situation if circumstances so warrant.

Another issue raised during the comment period is the question of the effect of §85.57 upon the requirements of the Architectural Barriers Act of 1968, Pub. L. 90-480. The relevant portion of that Act requires that, after 1968, all new construction and alteration receiving direct Federal financial assistance be accessible. One commenter feared that recipients who had undertaken construction subject to the Architectural Barriers Act but who had failed to comply with the Act might feel that compliance with the Architectural Barriers Act would be excused if its program, on the whole, were accessible and thus in compliance with §85.57. Such is not the case. The Department does not intend, and has no authority, to interfere in any way with the requirements of the Architectural Barriers Act.

Two comments requested that an exception be added to §85.57 for modifications of historic structures. While we agree that it is important to preserve historical structures, we believe that the flexibility of the program accessibility standard will permit recipients, with appropriate technical assistance and advice, to make their programs accessible without impairing the integrity of historic buildings.

Paragraph (c), added in response to comment, requires that transition plans be developed in cases where structural modifications are necessary to achieve program accessibility. The schedule for completion of these plans, as well as any further requirements deemed appropriate, is left to the determination of each regulating agency. The plan is to be developed with the aid of handicapped persons or their organizations.

Section 85.58 requires new facilities and, to the maximum extent feasible, alterations in existing facilities to be readily accessible. No accessibility standards have been specified here, but agencies should note that the HEW section 504 regulation requires HEW recipients either to meet the standards developed by the American National Standards Institute, Inc. (ANSI), or to provide equivalent accessibility. Each agency should, in the interest of governmentwide consistency, carefully consider adoption of the ANSI standards or their equivalent for any of its programs to which the standards are applicable.

A difficult problem that has arisen during the comment period with respect to §85.58 is its effect upon buses ordered in the interval between the final issuance of individual agency 504 regulations and the effective date of the Department of Transportation's ruling concerning Transbus. (That ruling requires that all buses acquired with the assistance of the Urban Mass Transportation Administration (UMTA), ordered after September 30, 1979, meet the specifications for Transbus—a low-floor, ramped bus.) Because of the complexity of the bus accessibility issue, the final regulation has been amended to allow the Department of Transportation (DOT) to defer the effective date for requiring all new buses to be accessible if DOT concludes during its section 504 rulemaking process that it is not possible to do so by the effective date of its own section 504 regulation and if comparable, accessible services are available to handicapped persons in the meantime. The date may not, however, be deferred beyond the present effective date of the Transbus decision—October 1, 1979.

Because this Department agrees that Transbus is the most effective means of providing handicapped persons with accessible bus transportation, it encourages the Department of Transportation to take all possible steps to expedite the purchase of Transbus by its recipients.

The effective date of this regulation is January 13, 1978. Because the regulation applies only to other federal agencies rather than to the public and because the governmentwide implementation of section 504 should proceed without further delay, the Department believes that this departure from the normal 30-day waiting period is warranted.

NOTE.—The Department of Health, Education, and Welfare has determined that this document does not contain a major proposal requiring preparation of an economic impact analysis (EIA) statement under Executive Orders 11821 and 11949 and OMB Circular A-107.

In consideration of the foregoing, Part 85 is hereby added to Title 45 of the Code of Federal Regulations to read as set forth below.

Dated: January 3, 1978.

JOSEPH A. CALIFANO, Jr.,
Secretary.

AUTHORITY: Executive Order 11914, 41 FR 17871; sec. 504, Rehabilitation Act of 1973, Pub. L. 93-112, 87 Stat. 394 (29 U.S.C. 794); sec. 111(a), Rehabilitation Act Amendments of 1974, Pub. L. 93-516, 88 Stat. 1619 (29 U.S.C. 706).

Subpart A—Federal Agency Responsibilities

§85.1 Purpose.

The purpose of this part is to implement Executive Order 11914, which requires the Department of Health, Education, and Welfare to coordinate the implementation of section 504 of the Rehabilitation Act of 1973.

§85.2 Application.

This part applies to each Federal department and agency that is empowered to extend Federal financial assistance.

§85.3 Definitions.

As used in this regulation, the term:

(a) "Executive order" means Executive Order 11914, titled "Nondiscrimination with respect to the Handicapped in Federally Assisted Programs," issued on April 28, 1976.

(b) "Section 504" means section 504 of the Rehabilitation Act of 1973, Pub. L. 93-112, as amended by the Rehabilitation Act Amendments of 1974, Pub. L. 93-516, 29 U.S.C. 794.

(c) "Agency" means a Federal department or agency that is empowered to extend financial assistance.

(d) "Recipient" means any State or its political subdivision, any instrumentality of a State or its political subdivision, any public or private agency, institution, organization, or other entity, or any person to which Federal financial assistance is extended directly or through another recipient, including any successor, assignee, or transferee of a recipient, but excluding the ultimate beneficiary of the assistance.

(e) "Federal financial assistance" means any grant, loan, contract (other than a procurement contract or a contract of insurance or guaranty), or any other arrangement by which the agency provides or otherwise makes available assistance in the form of:

(1) Funds;

(2) Services of Federal personnel; or

(3) Real and personal property or any interest in or use of such property, including:

(i) Transfers or leases of such property for less than fair market value or for reduced consideration; and

(ii) Proceeds from a subsequent transfer or lease of such property if the Federal share of its fair market value is not returned to the Federal Government.

(f) "Facility" means all or any portion of buildings, structures, equipment, roads, walks, parking lots, or other real or personal property or interest in such property.

§ 85.4 Issuance of agency regulations.

(a) Each agency shall issue, after notice and opportunity for comment, a regulation to implement section 504 with respect to the programs and activities to which it provides assistance. The regulation shall be consistent with this part.

(b) Each agency shall issue a notice of proposed rulemaking no later than 90 days after the effective date of this part. Each agency shall issue a final regulation no later than 135 days after the end of the period for comment on its proposed regulation: *Provided*, That the agency shall submit its proposed final regulation to the Director of the Office for Civil Rights, HEW, for review at least 45 days before it is to be issued.

(c) Each such agency regulation shall: (1) Define appropriate terms, consistent with the definitions set forth in § 85.3 and with the standards for determining who are handicapped persons set forth in Subpart B of this Part; and (2) prohibit discriminatory practices against qualified handicapped persons in employment and in the provision of aid, benefits, or services, consistent with the guidelines set forth in Subpart C of this Part. The regulation shall include, where appropriate, specific provisions adapted to the particular programs and activities receiving financial assistance from the agency.

§ 85.5 Enforcement.

(a) Each agency shall establish a system for the enforcement of section 504 and its implementing regulation with respect to the programs and activities to which it provides assistance. The system shall include: (1) The enforcement and hearing procedures that the agency has adopted for the enforcement of title VI of the Civil Rights Act of 1964, and (2) a requirement that recipients sign assurances of compliance with section 504.

(b) Each agency regulation shall also include requirements that recipients: (1) Notify employees and beneficiaries of their rights under section 504, (2) conduct a self-evaluation of their compliance with section 504, with the assistance of interested persons, including handicapped persons or organizations representing handicapped persons, and (3) otherwise consult with interested persons, including handicapped persons or organizations representing handicapped persons, in achieving compliance with section 504.

§ 85.6 Interagency cooperation.

(a) Where each of a substantial number of recipients is receiving assistance for similar or related purposes from two or more agencies or where two or more agencies cooperate in administering assistance for a given class of recipients, the agencies shall: (1) Coordinate compliance with section 504, and (2) designate one of the agencies as the primary agency for section 504 compliance purposes.

(b) Any agency conducting a compliance review or investigating a compliant of an alleged section 504 violation shall notify any other affected agency upon discovery of its jurisdiction and shall inform it of the findings made. Reviews or investigations may be made on a joint basis.

§ 85.7 Coordination with sections 502 and 503.

(a) Agencies shall consult with the Architectural and Transportation Barriers Compliance Board in developing requirements for the accessibility of new facilities and alterations, as required in § 85.58, and shall coordinate with the Board in enforcing such requirements with respect to facilities that are subject to section 502 of the Rehabilitation Act of 1973, as amended, as well as to section 504.

(b) Agencies shall coordinate with the Department of Labor in enforcing requirements concerning employment discriminination with respect to recipients that are also federal contractors subject to section 503 of the Rehabilitation Act of 1973, as amended.

§§ 85.8-85.30 [Reserved]

Subpart B—Standards for Determining Who are Handicapped Persons

§ 85.31 Handicapped person.

(a) "Handicapped person" means any person who has a physical or mental impairment that substantially limits one or more major life activities, has a record of such an impairment, or is regarded as having such an impairment.

(b) As used in paragraph (a) of this section, the phrase:

(1) "Physical or mental impairment" means (i) any physiological disorder or condition, cosmetic disfigurement, or anatomical loss affecting one or more of the following body systems: Neurological; musculoskeletal; special sense organs; respiratory, including speech organs; cardiovascular; reproductive; digestive; genitourinary; hemic and lymphatic; skin; and endocrine; or (ii) any mental or psychological disorder, such as mental retardation, organic brain syndrome, emotional or mental illness, and specific learning disabilities. The term "physical or mental impairment" includes, but is not limited to, such diseases and conditions as orthopedic, visual, speech, and hearing impairments, cerebral palsy, epilepsy, muscular dystrophy, multiple sclerosis, cancer, heart disease, diabetes, mental retardation, emotional illness, and drug addiction and alcoholism.

(2) "Major life activities" means functions such as caring for one's self, performing manual tasks, walking, seeing, hearing, speaking, breathing, learning, and working.

(3) "Has a record of such an impairment" means has a history of, or has been misclassified as having, a mental or physical impairment that substantially limits one or more major life activities.

(4) "Is regarded as having an impairment" means (i) has a physical or mental impairment that does not substantially limit major life activities but is treated by a recipient as constituting such a limitation; (ii) has a physical or mental impairment that substantially limits major life activities only as a result of the attitudes of others toward such impairment; or (iii) has none of the impairments defined in paragraph (b)(1) of this section but is treated by a recipient as having such an impairment.

§ 84.32 Qualified handicapped person.

"Qualified handicapped person" means (a) with respect to employment, a handicapped person who, with reasonable accommodation, can perform the essential functions of the job in question and (b) with respect to services, a handicapped person who meets the essential eligibility requirements for the receipt of such services.

§§ 85.33-85.50 [Reserved]

Subpart C—Guidelines for Determining Discriminatory Practices

GENERAL

§ 85.51 General prohibitions against discrimination.

(a) No qualified handicapped person, shall, on the basis of handicap, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any program or activity that receives or benefits from federal financial assistance.

(b)(1) A recipient, in providing any aid, benefit, or service, may not, directly or through contractual, licensing, or other arrangements, on the basis of handicap:

(i) Deny a qualified handicapped person the opportunity to participate in or benefit from the aid, benefit, or service;

(ii) Afford a qualified handicapped person an opportunity to participate in or benefit from the aid, benefit, or service that is not equal to that afforded others;

(iii) Provide a qualified handicapped person with an aid, benefit, or service that is not as effective in affording equal opportunity to obtain the same result, to gain the same benefit, or to reach the same level of achievement as that provided to others;

(iv) Provide different or separate aid, benefits, or services to handicapped persons or to any class of handicapped persons than is provided to others unless such action is necessary to provide qualified handicapped persons with aid, benefits, or services that are as effective as those provided to others;

(v) Aid or perpetuate discrimination against a qualified handicapped person by providing significant assistance to an agency, organization, or person that discriminates on the basis of handicap in providing any aid, benefit, or service to beneficiaries of the recipient's program;

(vi) Deny a qualified handicapped person the opportunity to participate as a member of planning or advisory boards; or

(vii) Otherwise limit a qualified handicapped person in the enjoyment of any right, privilege, advantage, or opportunity enjoyed by others receiving the aid, benefit, or service.

(2) A recipient may not deny a qualified handicapped person the opportunity to participate in programs or activities that are not separate or different, despite the existence of permissibly separate or different programs or activities.

(3) A recipient may not, directly or through contractual or other arrangements, utilize criteria or methods of administration (i) that have the effect of subjecting qualified handicapped persons to discrimination on the basis of handicap, (ii) that have the purpose or effect of defeating or substantially impairing accomplishment of the objectives of the recipient's program with respect to handicapped persons, or (iii) that perpetuate the discrimination of another recipient if both recipients are subject to common administrative control or are agencies of the same state.

(4) A recipient may not, in determining the site or location of a facility, make selections (i) that have the effect of excluding handicapped persons from, denying them the benefits of, or otherwise subjecting them to discrimination under any program or activity that receives or benefits from federal financial assistance or (ii) that have the purpose or effect of defeating or substantially impairing the accomplishment of the objectives of the program or activity with respect to handicapped persons.

(c) The exclusion of nonhandicapped persons from the benefits of a program limited by federal statute or executive order to handicapped persons or the exclusion of a specific class of handicapped persons from a program limited by federal statute or executive order to a different class of handicapped persons is not prohibited by this part.

(d) Recipients shall administer programs and activities in the most integrated setting appropriate to the needs of qualified handicapped persons.

(e) Recipients shall take appropriate steps to ensure that communications with their applicants, employees, and beneficiaries are available to persons with impaired vision and hearing.

EMPLOYMENT

§ 85.52 General prohibitions against employment discrimination.

(a) No qualified handicapped person shall, on the basis of handicap, be subjected to discrimination in employment under any program or activity that receives or benefits from federal financial assistance.

(b) A recipient shall make all decisions concerning employment under any program or activity to which this part applies in a manner which ensures that discrimination on the basis of handicap does not occur and may not limit, segregate, or classify applicants or employees in any way that adversely affects their opportunities or status because of handicap.

(c) The prohibition against discrimination in employment applies to the following activities:

(1) Recruitment, advertising, and the processing of applications for employment;

(2) Hiring, upgrading, promotion, award of tenure, demotion, transfer, layoff, termination, right of return from layoff, and rehiring;

(3) Rates of pay or any other form of compensation and changes in compensation;

(4) Job assignments, job classifications, organizational structures, position descriptions, lines of progression, and seniority lists;

(5) Leaves of absence, sick leave, or any other leave;

(6) Fringe benefits available by virtue of employment, whether or not administered by the recipient;

(7) Selection and financial support for training, including apprenticeship, professional meetings, conferences, and other related activities, and selection for leaves of absence to pursue training;

(8) Employer sponsored activities, including social or recreational programs; and

(9) Any other term, condition, or privilege of employment.

(d) A recipient may not participate in a contractual or other relationship that has the effect of subjecting qualified handicapped applicants or employees to discrimination prohibited by this subpart. The relationships referred to in this paragraph include relationships with employment and referral agencies, with labor unions, with organizations providing or administering fringe benefits to employees of the recipient, and with organizations providing training and apprenticeship programs.

§ 85.53 Reasonable accommodation.

A recipient shall make reasonable accommodation to the known physical or mental limitations of an otherwise qualified handicapped applicant or employee unless the recipient can demonstrate that the accommodation would impose an undue hardship on the operation of its program.

§ 85.54 Employment criteria.

A recipient may not use employment tests or criteria that discriminate against handicapped persons and shall ensure that employment tests are adapted for use by persons who have handicaps that impair sensory, manual, or speaking skills.

§ 85.55 Preemployment inquiries.

A recipient may not conduct a preemployment medical examination or make a preemployment inquiry as to whether an applicant is a handicapped person or as to the nature or severity of a handicap except under the circumstances described in 45 CFR 84.14.

PROGRAM ACCESSIBILITY

§ 85.56 General requirement concerning program accessibility.

No qualified handicapped person shall, because a recipient's facilities are inaccessible to or unusable by handicapped persons, be denied the benefits of, be excluded from participation in, or otherwise be subjected to discrimination under any program or activity that receives or benefits from federal financial assistance.

§ 85.57 Existing facilities.

(a) A recipient shall operate each program or activity so that the program or activity, when viewed in its entirety, is readily accessible to and usable by handicapped persons. This paragraph does not necessarily require a recipient to make each of its existing facilities or every part of an existing facility accessible to and usable by handicapped persons.

(b) Where structural changes are necessary to make programs or activities in existing facilities accessible, such changes shall be made as soon as practicable, but in no event later than three years after the effective date of the agency regulation: *Provided*, That, if the program is a particular mode of transportation (e.g., a subway system) that can be made accessible only through extraordinarily expensive structural changes to, or replacement of, existing facilities and if other accessible modes of transportation are available, the federal agency responsible for enforcing section 504 with respect to that program may extend this period of time, but only for a reasonable and definite period, such period to be set forth in the agency's regulation.

(c) In the event that structural changes to facilities are necessary to meet the requirement of paragraph (a) of this section, a recipient shall develop, within a definite period to be established in each agency's regulation, a transition plan setting forth the steps necessary to complete such changes. The plan shall be developed with the assistance of interested persons, including handicapped persons or organizations representing handicapped persons.

§ 85.58 New construction.

(a) Except as provided in paragraph (b) of this section, new facilities shall be designed and constructed to be readily accessible to and usable by handicapped persons. Alterations to existing facilities shall, to the maximum extent feasible, be designed and constructed to be readily accessible to and usable by handicapped persons.

(b) The Department of Transportation may defer the effective date for requiring all new buses to be accessible if it concludes on the basis of its section 504 rulemaking process that it is not feasible to require compliance on the effective date of its regulation: *Provided*, That comparable, accessible services are available to handicapped persons in the interim and that the date is not deferred later than October 1, 1979.

§§ 85.59-85.99 [Reserved]

APPENDIX A.—NONDISCRIMINATION WITH RESPECT TO THE HANDICAPPED IN FEDERALLY ASSISTED PROGRAMS

EXECUTIVE ORDER 11914, APRIL 28, 1976

By virtue of the authority vested in me by the Constitution and statutes of the United States of America, including section 301 of title 3 of the United States Code, and as President of the United States, and in order to provide for consistent implementation within the Federal Government of section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), it is hereby ordered as follows:

SECTION 1. The Secretary of Health, Education, and Welfare shall coordinate the implementation of section 504 of the Rehabilitation Act of 1973, as amended, hereinafter referred to as section 504, by all Federal departments and agencies empowered to extend Federal financial assistance to any program or activity. The Secretary shall establish standards for determining who are handicapped individuals and guidelines for determining what are discriminatory practices, within the meaning of section 504. The Secretary shall assist Federal departments and agencies to coordinate their programs and activities and shall consult with such departments and agencies, as necessary, so that consistent policies, practices, and procedures are adopted with respect to the enforcement of section 504.

SEC. 2. In order to implement the provisions of section 504, each Federal department and agency empowered to provide Federal financial assistance shall issue rules, regulations, and directives, consistent with the standards and procedures established by the Secretary of Health, Education, and Welfare.

SEC. 3. (a) Whenever the appropriate department or agency determines, upon all the information available to it, that any recipient of, or applicant for, Federal financial assistance is in noncompliance with the requirements adopted pursuant to this order, steps to secure voluntary compliance shall be carried out in accordance with standards and procedures established pursuant to this order.

(b) If voluntary compliance cannot be secured by informal means, compliance with section 504 may be effected by the suspension or termination of, or refusal to award or continue, Federal financial assistance or by other appropriate means authorized by law, in accordance with standards and procedures established pursuant to this order.

(c) No such suspension or termination of, or refusal to award or continue, Federal financial assistance shall become effective unless there has been an express finding, after opportunity for a hearing, of a failure by the recipient of, or applicant for, Federal financial assistance to comply with the requirements adopted pursuant to this order; however, such suspension or termination of, or refusal to award or continue, Federal financial assistance shall be limited in its effect to the particular program or activity or part thereof with respect to which there has been such a finding of noncompliance.

SEC. 4. Each Federal department and agency shall furnish the Secretary of Health, Education, and Welfare such reports and information as the Secretary requests and shall cooperate with the Secretary in the implementation of section 504.

SEC. 5. The Secretary of Health, Education, and Welfare may adopt rules and regulations and issue orders which he deems are necessary to carry out his responsibilities under this order. The Secretary shall ensure that such rules, regulations, and orders are not inconsistent with, or duplicative of, other Federal Government policies relating to the handicapped, including those policies adopted in accordance with sections 501, 502, and 503 of the Rehabilitation Act of 1973, as amended, or the Architectural Barriers Act of 1968 (42 U.S.C. 4151 *et seq.*).

GERALD R. FORD

The White House,
April 28, 1976.

[FR Doc. 78-929 Filed 1-12-78; 8:45 am]

federal register

FRIDAY, JANUARY 13, 1978
PART VI

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

BLOOD AND BLOOD PRODUCTS

Donor Classification Labeling Requirements

[4110-03]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER F—BIOLOGICS
[Docket No. 75N-0316]

PART 606—CURRENT GOOD MANUFACTURING PRACTICES FOR BLOOD AND BLOOD COMPONENTS

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

Whole Blood and Components of Whole Blood Intended for Transfusion; Donor Classification Labeling Requirements

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This rule amends the Food and Drug Administration (FDA) biologics regulations by requiring that each container of whole blood and blood components (red blood cells, cryoprecipitated antihemophilic factor, platelet concentrate, and single donor plasma) intended for transfusion bear the label statement "paid donor" or "volunteer donor," as applicable. The regulation is designed to reduce the risk of hepatitis associated with transfusion therapy.

EFFECTIVE DATE: May 15, 1978.

FOR FURTHER INFORMATION CONTACT:

Joe K. Holloway or Al Rothschild, Bureau of Biologics (HFB-620), Food and Drug Administration, Department of Health, Education, and Welfare, 8800 Rockville Pike, Bethesda, Md. 20014, 301-443-4626.

SUPPLEMENTARY INFORMATION: In two separate notices published in the FEDERAL REGISTER of November 14, 1975 (40 FR 53040), and February 25, 1977 (42 FR 11018), the Commissioner of Food and Drugs proposed to amend the biologics regulations to require that the labels of blood products distinguish between blood collected from volunteer donors and paid donors. In the initial proposal, the Commissioner also required that the labels for paid-donor blood contain a warning that such blood is associated with a higher risk of transmitting hepatitis than blood from volunteer donors.

The Commissioner concluded that the proposed labeling requirements would promote the use of blood from donors who are from sectors of society in which transmissible viral hepatitis, type B, is less prevalent and would thereby reduce the risk of hepatitis associated with transfusion therapy. In support of this conclusion, the Commissioner discussed published data regarding the incidence of posttransfusion hepatitis from use of blood which had and had not been tested for hepatitis B surface antigen (HB_sAg), the prevalence of HB_sAg in the blood of paid donors, and the reduced incidence of posttransfusion hepatitis after elimination of use of paid-donor blood. The Commissioner concluded that the published data demonstrate that blood collected from paid donors is distinguishable from blood collected from volunteer donors in terms of the potential hazard, and that the decreased use of blood from paid donors would have a greater impact in reducing the incidence of posttransfusion hepatitis than any other measure, including HB_sAg testing.

The Commissioner stated his belief that the proposed requirement for label disclosure identifying the source of whole blood and its components (1) is necessary in order to provide physicians who prescribe blood with this important information, (2) is consistent with the National Blood Policy objective to encourage, foster, and support efforts to establish an all-voluntary blood donation system, (3) will not interrupt blood services now provided, (4) will significantly increase the demand for blood from volunteer donors or blood from paid donors collected by blood banks having evidence that their donor population is as safe as volunteer donor populations, and (5) will reduce the risk of transmitting hepatitis via transfusion therapy.

The Commissioner also discussed in detail the statutory authority for proposing the labeling requirements.

Interested persons were given until January 13, 1976, to submit written comments to the first proposal. In response, 342 letters were received. A majority of the comments recommended that the proposal be reissued to include a proposed definition for the terms "paid donor" and "volunteer donor".

The Commissioner agreed that "paid donor" and "volunteer donor" should be defined in the regulations. Accordingly, he issued a notice, published in the FEDERAL REGISTER of February 3, 1976 (41 FR 4955), requesting interested persons to submit data and information for use in formulating a definition for "paid donor" and "volunteer donor". In response, 331 additional letters were received.

Because of the intense, widespread interest in and the public importance of the proposed labeling requirements, the Commissioner, in a notice published in the FEDERAL REGISTER of February 27, 1976 (41 FR 8523), announced and later convened a public meeting on March 18, 1976, to discuss the following subjects:

1. Data documenting the risk of posttransfusion hepatitis associated with blood collected from volunteer and paid donors.
2. Summary of comments received in response to the FEDERAL REGISTER proposal of November 14, 1975.
3. Recommendations for a reproposal, including definitions for "volunteer" and "paid" donors and other suggestions recommended in the comments on the November 1975 proposal.
4. General discussion of various viewpoints on the proposal.

In response to the comments received on the November 1975 proposal, on the February 3, 1976, notice, and at the March 1976 public meeting, the Commissioner published another proposal in the FEDERAL REGISTER of February 25, 1977, to require that each container of whole blood and blood components (red blood cells, cryoprecipitated antihemophilic factor, platelet concentrate, and single donor plasma) intended for transfusion bear the label statement "Paid Donor" or "Volunteer Donor", as applicable. In addition, the Commissioner proposed definitions for paid and volunteer donors.

The February 1977 proposal differed from the November 1975 proposal in that it made the labeling requirements applicable to all blood components intended for transfusion rather than to only whole blood and red blood cells. The February 1977 proposal did not, however, repropose the warning statement concerning the increased risks of hepatitis from blood collected from paid donors. The reasons for the deletion were discussed in detail in the February 1977 proposal.

In response to the February 1977 proposal, 165 letters, containing varying numbers of comments, were received. Approximately 103 letters favored and 62 opposed the proposal.

In general, the comments addressed three aspects of the proposal: (1) the definitions and interpretations of paid and volunteer donors and the mechanics of labeling, (2) the effect of labeling on safety, and (3) the effect of labeling on supply and cost of blood and blood products.

DEFINITIONS AND MECHANICS OF LABELING

1. Four comments agreeing with the proposed definitions noted that the definitions are equivalent or identical to those already established by the American Association of Blood Banks. One comment, although supporting the proposed definitions in principle, suggested that the adjectives "paid" and "volunteer" should be replaced with "reimbursed" and "nonreimbursed," respectively. One other comment suggested that a code be used on the label to identify the "paid" or "volunteer" donor.

The Commissioner is aware that various other words and phrases or even a code might be used to convey the desired information. However, they provide no more clarification than do the terms "paid" and "volunteer," which terms "paid" and "volunteer," which are currently being used by the States of Illinois, California, Georgia, and Florida under their blood labeling laws. In addition, the American Red Cross, which collects only from volunteer donors, identifies its blood as "volunteer donor" blood. Accordingly, the substitute terminology is rejected.

2. Nineteen comments suggested that the term "paid" donor include a person who receives: (1) a large amount of time off from work, (2) additional vacation time, (3) rewards generally used as a motivation for donation, such as lotteries, giveaways, a chance interest in a prize with significant dollar value, or nonmonetary rewards associated with product promotion, (4) reduction or cancellation of hospital charges that are unrelated to the transfusion, and (5) the cancellation or refund of nonreplacement fees and blood assurance/insurance benefits.

As stated in the preambles of both the 1975 and 1977 proposals, the high risk of posttransfusion hepatitis associated with blood from paid donors primarily reflects the fact that direct monetary payment attracts and motivates donations from individuals in unfortunate socioeconomic circumstances in whom transmissible hepatitis is particularly prevalent, including drug addicts who are in desperate need of money to purchase drugs. Benefits which are not readily convertible to cash, such as those identified in the comments, are not likely to attract those groups in which transmissible hepatitis is prevalent. For this reason, the Commissioner concludes that donors receiving such benefits should not be classified as paid donors. Accordingly, the comments are rejected.

The Commissioner notes that in amended § 606.120, paragraph (b)(2)(iii) provides that benefits not readily convertible to cash do not constitute monetary payment for purposes of this labeling regulation. The basic definitions of "paid" and "volunteer" donors turn on the direct, clear, and thus enforceable distinction between the exchange or absence of exchange of money.

3. Nine comments suggested that the proposed labeling also distinguish between safe and unsafe paid donors. Some large institutional blood banks, such as hospitals and community blood banks, screen paid donors so that they have a lower incidence of HB_sAg than do some volunteer donor populations. The comments suggested that paid donors be categorized as either "paid noncommercial" or "paid commercial" as a shorthand way to distinguish between safe (low-risk) and unsafe (high-risk) donors. One of the comments also suggested that a distinction be made on the label between low-risk and high-risk volunteers.

As these comments demonstrate, a number of categories and distinguishing characteristics could be applied to blood donors. The definitions proposed by the Commissioner for "paid donor" and "volunteer donor" are widely recognized in the blood community and provide basic information without the confusion that might arise from the addition of new donor categories as they are identified. The subcategories suggested by the comment are not as generally recognized or understood as are the "paid" and "volunteer" donor categories. Accordingly, the comments are rejected.

4. Twelve comments suggested that the Commissioner require the donor classification statement to be changed to "first time donor" or "repeat donor" instead of "paid donor" or "volunteer donor" because the risk of hepatitis in blood from first time donors, whether paid or volunteer, is greater than the risk from repeat donors, whose blood has already been biologically tested, i.e., followup monitoring of the recipient has shown no hepatitis transmission. It was argued that if blood from screened and tested repeat paid donors must be labeled "paid", it would be unnecessarily avoided by doctors, because of an implied but unsubstantiated risk, in favor of "volunteer" blood collected from high-risk urban ghetto or State prison populations.

The Commissioner recognizes that a small proportion of "paid donor" blood is being obtained from biologically tested donors whose hepatitis risk is as low as or lower than that from random volunteer donors. In those few situations, mechanisms are available for informing hospital administrators, physicians, and patients. The mechanisms include information in the package circular accompanying the blood unit and agreements between the blood bank and the purchasing hospitals and physicians. The Commissioner notes that no first-donation blood is biologically tested, and that, therefore, for these units of blood, the volunteer/paid labeling would continue to be necessary. Accordingly, the comments are rejected.

5. Thirteen comments stated that the proposed labeling requirements present an undue expense and hardship to most blood banks since 95 percent of all blood collected is from volunteer donors. The comments suggested that only blood from paid donors need be identified on the label.

The Commissioner believes that the absence of the term "volunteer donor" from blood units may raise questions of accountability. For example, the inadvertent failure to place the "paid donor" label on a unit will result in the assumption, possibly unwarranted and incorrect, by physicians and patients that the unit was collected from a volunteer donor. If identification of donor source is required for both paid and volunteer donors, an unlabeled unit will not result in unjustified reliance, and the recipient will be on notice to check with the collecting facility. In addition, the affirmative disclosure of the donor source on blood labeling will serve to inform patient consumers, who are not as likely as hospital administrators and physicians to be current on Federal labeling laws for blood and blood products.

The Commissioner reiterates his belief, stated in the preamble to the February 25, 1977 proposal, that any cost increase resulting from the proposed labeling requirement will be minimal. All whole blood products for transfusion must bear a label with significant information. The donor classification can be included on the labels along with the currently required information and incorporated as new labels are printed. The effective date of this regulation should permit an orderly transition to the new labels. Accordingly, the comments are rejected.

6. Four comments stated that the proposed labeling requirement should be applicable to Source Plasma (Human) since the incidence of HB_sAg positive units is greater in this product than in whole blood or single donor components intended for transfusion. On the other hand, six comments requested that proposed § 606.120(b)(2) be amended to exempt Source Plasma (Human) from the proposed labeling requirement.

As stated in the February 1977 proposal, the Commissioner is not aware of any data to support the use of the proposed labeling requirements for Source Plasma (Human) or plasma derivatives. Although data have been published demonstrating a higher prevalence of HB_sAg in plasma from paid donors than in plasma from volunteer donors, no available data demonstrate that final plasma derivative products manufactured from volunteer donor plasma carry a lower risk of transmitting hepatitis to recipients than do similar products manufactured from paid donor plasma. Most types of derivative products are processed in a manner which destroys or removes the hepatitis virus. Accordingly, no established public health benefit can derive from requiring donor labeling on Source Plasma (Human); and such information, therefore, is not a material fact. Therefore, the Commissioner is amending § 606.120(b)(2) to exempt Source Plasma (Human).

7 a. One comment stated that blood is not a drug and therefore should not be subject to the proposed labeling requirements.

b. Three related comments stated that the proposed labeling represents an unauthorized attempt by FDA to implement the National Blood Policy calling for an all-volunteer blood supply since the labeling is not sanctioned by statute and the policy is being implemented by an ad hoc coalition of government and private institutions.

These issues were thoroughly answered in the preamble of the November 1975 proposal. A summary of that discussion, and the legal basis for the blood good manufacturing practice regulations, of which the drug classification labeling is a part, is repeated here.

a. Blood and blood components are drugs as defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)) since they are used to treat disease, they affect bodily functions, and whole blood is recognized in the United States Pharmacopeia. As drugs, they must meet all statutory requirements of the Federal Food, Drug, and Cosmetic Act and are subject to regulation pursuant to all provisions of the act.

The donor classification labeling constitutes important information about the blood quality and gives notice of the potential adverse consequences from its use, namely, the documented increased risk of transmitting hepatitis from use of blood from paid donors. Failure to reveal this material fact renders blood labeling to be misleading (21 U.S.C. 321(n)) and results in the blood being misbranded (21 U.S.C. 352(a)) within the meaning of the act. The act also requires adequate warnings in drug labeling (21 U.S.C. 352(f)). In addition, a drug is adulterated (21 U.S.C. 351(a)(2)(B)) if it has not been manufactured in conformity with current good manufacturing practice. Pursuant to these statutory provisions, the Commissioner may promulgate regulations for essential information on blood labeling.

Jurisdiction under the act is not limited to situations where the blood itself has been, or is to be, introduced into interstate commerce. If one of the essential components of blood, such as the anticoagulant solution, has moved in interstate commerce, the blood is subject to the requirements of the act and FDA may regulate the final drug product (21 U.S.C. 321(g)(1)(D)). The Federal courts have uniformly upheld this scope of authority.

All blood and blood components offered for sale in interstate commerce are also biological products and are therefore also subject to the Public Health Service Act (42 U.S.C. 262). All manufacturers must have a license that has been issued upon a showing that the manufacturing establishment and its products meet all applicable standards prescribed in the biologics regulations. Regulations may be promulgated to assure proper labeling for any biological product (42 U.S.C. 262(d)), and the Public Health Service Act prohibits the false labeling or marking of any package or container of any biological product (42 U.S.C. 262(b)). Moreover, the prohibition against false labeling in this act contains no interstate commerce requirement; it applies to all blood, whether or not it has moved or is offered for sale in interstate commerce. When blood labels do not affirmatively reveal the donor source, they are false by reason of omission. Finally, the Commissioner is authorized to promulgate regulations, pursuant to 42 U.S.C. 264, which may be necessary to prevent the transmission of such blood-related communicable diseases as hepatitis. Thus, the Public Health Service Act equally and independently supports the donor classification labeling requirement.

b. There is nothing unlawful or improper with the Commissioner promulgating a regulation incorporating a policy advocated by any citizen or group, including members of regulated industry. The Commissioner routinely receives and considers the views of industry and individuals in the private sector. The Commissioner also gathers information by corresponding and meeting with interested persons outside FDA regarding any matter within the jurisdiction of the laws administered by him. All interested persons are afforded the opportunity to have their comments, favorable or otherwise, considered in the development of final rules that may have resulted from the meetings with the private sector or with representatives of industry. Even if the National Blood Policy were solely the product of the private sector, which it is not (see FEDERAL REGISTER of September 10, 1974 (39 FR 32702)) the two proposals and the public meeting on the donor classification labeling have provided every opportunity for comment by any interested person. Accordingly, the suggestion that the regulation is deficient because it will enhance one of the goals of the National Blood Policy is erroneous.

8. Four comments advocated retention of the warning statement, "blood collected from paid donors is associated with a higher risk of transmitting hepatitis than blood from voluntary donors," as originally proposed in November 1975.

The Commissioner reaffirms his decision, announced in the preamble to the February 1977 proposal, not to require the warning statement initially included in the November 1975 proposal. The designation of blood as to its source, paid or volunteer, is concise and adequate notification to physicians of the relative risk of hepatitis associated with the blood. The evidence of the association between paid donors and increased risk of hepatitis, delineated in the November 1975 proposal, was mailed directly to all blood banks registered with FDA. A brief synopsis of the proposal, emphasizing the high risk of hepatitis associated with blood from paid donors, was published in the FDA Drug Bulletin of April-May 1976, which is mailed to all physicians in the United States.

The American Blood Commission, an association within the private sector working towards implementation of the National Blood Policy, has urged the creation of an all-voluntary blood donor system because of the statistical association between paid donors and the transmission of hepatitis in blood therapy. The work of the Commission and its policies and publications are well known throughout the entire blood processing community. Also, the question of designating blood as being "paid" or "volunteer" has been aired not only in the medical literature but frequently in the lay press and on radio and television.

Four States with effective blood labeling laws—Illinois, California, Georgia, and Florida—do not require an additional warning statement. The experiences in these States, particularly in Illinois where this law has been in effect for several years, support the necessity for only a brief descriptive term without an explicit warning of the probability of infection.

Notwithstanding these data given to physicians, the Commissioner will propose a warning statement if it appears that responsible heads of blood banks, administrators, and purchasing agents of hospitals, physicians, or consumers are not adequately apprised of the facts.

9. One comment questioned whether the labeling of the donor source would continue in an all-volunteer system.

The Commissioner anticipates that in an all-volunteer system there would be no need for labeling to distinguish paid donors from volunteer donors.

10. One comment suggested that the donor source need not appear with the same prominence as the proper name. The comment noted that the American Red Cross labeling includes the donor source in smaller, less prominent type and away from the proper name.

The Commissioner has concluded that the donor source is of such importance that it must be stated conspicuously with the same prominence as the proper name of the product. (See 21 U.S.C. 352(c).) Accordingly, the comment is rejected.

EFFECT OF LABELING ON SAFETY OF THE PRODUCT

11. Twenty-nine comments suggested that the proposed labeling is unnecessary and should be withdrawn since (1) no scientific data have been presented to support the fact that a label

will insure the safety of transfused blood, (2) no information has been presented to show that the labeling will significantly reduce the number of blood units which transmit disease, and (3) the rule is a superficial answer to a serious medical problem and therefore will not contribute to the solution. The comments suggested that the time and effort spent in putting an additional label on a unit of blood and/or component would only further clutter the label and will have no impact on the clinician who will transfuse it.

The Commissioner disagrees with these comments. As a result of the 1973 Illinois law that all blood collected in or transported into the State must prominently display whether it was collected from paid or volunteer donors, the number of units of purchased blood infused decreased by 35.2 percent despite a 15 percent increase in the number of transfusions (fiscal 1974 to fiscal 1975). Furthermore, the percentage of outdated blood fell from 15.4 percent to 12.9 percent in the same period.

In a study conducted at the Hines Veterans' Administration Hospital, Chicago, Ill., 20.8 percent of transfused patients developed posttransfusion hepatitis from 1968-70, when 92 percent of the hospital blood supply was obtained from paid donors. However, the incidence of hepatitis decreased by 62 percent, to a rate of 7.9 percent of transfused patients, when 96 percent of the hospital's blood supply was obtained from volunteer donors. Similarly, in New Jersey, during a period in which the proportion of blood obtained from paid donors decreased from 31 percent (1970) to 9 percent (1973), the number of overt cases of posttransfusion hepatitis decreased from 424 (1 per 117 transfused patients) (1970) to 159 (1 per 284 transfused patients) (1973). In addition, during 1961-70 and 1971-73, the rate of fatalities resulting from posttransfusion hepatitis decreased from 12.9 percent to 7.2 percent, respectively. The Commissioner believes that these experiences, reported in November 1975, demonstrate that the paid and volunteer labeling significantly aids in reducing the incidence of posttransfusion hepatitis, and that it also promotes blood therapy safety and is therefore a valid, albeit partial, answer to the problem. Accordingly, the comments are rejected.

12. Nine comments suggested that FDA develop a program to enhance effective screening by the blood or component collection facility, including the improvement of donor selection procedures, by such means as the taking of medical histories from prospective donors.

The good manufacturing practice regulations for blood products, § 606.100 Standard operating procedures (21 CFR 606.100), require that each blood bank have written procedures establishing criteria for donor suitability, including acceptable medical history criteria. The requisite standard operating procedures manual should describe the best current techniques and procedures and policies developed by blood banking practitioners. These procedures, together with FDA inspections, have stimulated and enhanced good blood banking practices. In addition, the Bureau of Biologics is revising new donor selection procedures that will update the donor suitability requirements. These procedures will be published in a separate proposal.

13. Four comments suggested that the data presented in the November 1975 proposal, which were relied upon to classify certain categories of donors as high-risk, are not persuasive. It was argued that the distinction between donors in some of the referenced studies was imprecise because the methods of hepatitis testing were less sensitive than the third generation test, and that other studies revealed persistent posttransfusion hepatitis associated with blood despite third generation HB_sAg testing. Accordingly, the comments suggested that conclusions drawn from these studies were not reliable.

The Commissioner disagrees. Data establishing certain categories of donors as high risk transmitters of hepatitis were supported by numerous studies conducted after the nationwide HB_sAg-testing requirements became effective, including the use of methods of third generation sensitivity (radioimmuno assay procedures (RIA)).

As stated in the preamble to the November 1975 proposal, there has been a continuing evolution of more sensitive methods for detecting the HB_sAg. However, the most sensitive methods presently available and required by FDA regulations, methods of third generation sensitivity, are expected to detect only about 40 to 60 percent of the units of blood containing the hepatitis B virus. For this reason, the risk of transmitting viral hepatitis type B has been reduced but not eliminated by the testing requirements. Indeed, studies conducted by the New Jersey Department of health of recipients of blood prescreened by RIA found the rate of hepatitis B virus infection in recipients of blood from volunteer donors to be 1.1 percent compared to 4.2 percent in recipients of blood from paid donors. (Ref. "An epidemiological study of transfusion-associated hepatitis" conducted November 17, 1975 through December 31, 1976). Further, the National Heart, Lung and Blood Institute of the National Institutes of Health found that elevated liver-specific enzymes, indicating hepatitis of all varieties, were seen in about 10 percent of prospectively followed recipients of blood from volunteer donors as compared to about 40 percent of similarly followed recipients of blood from paid donors. (Ref. "The transfusion transmitted virus" study conducted July 1, 1974 through December 31, 1975).

These recent studies demonstrate that the high posttransfusion hepatitis risk associated with blood from paid donors pesists despite third generation testing. The Commissioner concludes that the available data support a need for the donor classification labeling. Accordingly, the comments are rejected.

14. Ten comments expressed concern that the labeling requirements did not apply to blood imported into this country and that the country of origin is not required to be identified. The comments suggested that such provisions are necessary to ensure that blood will be from populations with no greater risk of hepatitis, or other diseases transmissible by blood, than for blood or components obtained from donors in the United States. The comments suggested that though most imports today are from Western Europe and from volunteers who may be low hepatitis-risk donors, there are no means to prevent importation of voluntary blood from Japan, Mexico, and Greece. The nutrition, sanitation, and general health in countries other than the United States vary widely, as does the understanding of what a "volunteer" is and the effectiveness of donor screening. The comments suggested that labeling a unit of blood with the country of origin will provide both physicians and patients some valuable information and thus assist in informed decisions as to blood use. The comments suggest there is no known import commodity that does not contain a legend as to its country of origin and that blood should conform to this general practice.

In the February 1977 proposal, the Commissioner advised that the proposed labeling requirements are applicable to blood and blood components shipped into this country from overseas. Blood and blood components intended for transfusion may be imported into this country only if the establishment and the product(s) are licensed. (See § 601.30 (21 CFR 601.30).) Licensed biological products, whether from a foreign or domestic establishment, must meet the same standards of safety, purity, potency, and effectiveness and must be labeled in compliance with the law. Therefore, biologics regulations governing donor suitability and screening also apply to foreign licenses. Any new foreign sources of blood or blood components will have to meet these requirements. Products from countries in which disease transmissible by blood transfusions are endemic in frequencies that exceed to any significant degree that of the U.S. have not, and will not, be licensed for U.S. distribution. Accordingly, there is no need to label blood to identify the country of origin and the comments are therefore rejected.

15. Five comments suggested it would be simpler if FDA did not license blood banks that collect from high-incidence populations, such as the centers that regularly draw donors from skid-row areas, irrespective of whether the donors are paid or volunteer.

Establishments licensed pursuant to the Public Health Service Act (42 U.S.C. 262) to operate in interstate commerce are inspected prior to licensure and annually thereafter. Blood banks operating intrastate must be registered pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) and are inspected at least biannually. All blood banks must conform to blood GMP's (21 CFR Part 606), including the provisions governing donor suitability. Licensed banks violating these regulations are subject to having their licenses revoked (21 CFR 601.5); registered banks are subject to injunction action and Federal seizure of any adulterated or misbranded blood products. The Commissioner believes these safeguards are adequate. The Food and Drug Administration will continue to monitor closely the product obtained at all blood banks. Accordingly, the comments are rejected.

16. Eight comments objected to a statement in the February 1977 preamble suggesting that the proposed label would significantly increase the demand for blood from volunteer donors and from paid donors with no higher risk than volunteer donors. The objections were based on the fact that the Commissioner has not established definitive criteria, such as procedures for followup of posttransfusion hepatitis episodes, for determining when a paid donor population is as safe as a volunteer donor population. Three other comments, however, suggested that in addition to the labeling requirement, blood banks that rely on paid donors should be required to demonstrate the safety of the blood. The comments added that these requirements would encourage blood banks that continue to rely on paid donors to provide continuing evidence that their donor populations are comparable to the volunteer donor population.

The Commissioner agrees that Federal standards for biological testing of paid donors to demonstrate the safety of their blood are desirable. However, several important variables compound the task:

(1) Whether a donor population will transmit hepatitis can only be established once it is biologically tested. However, the population will always be a mixture of tested individuals who have donated previously and untested first-time donors. Also, donors may get hepatitis after the initial biological testing, altering their prior status.

(2) Establishing rates of posttransfusion hepatitis in transfused patients is seriously complicated by the infusion of whole blood components and derivatives from many sources into one patient; thus identifying the hepatitis source and reporting cases of posttransfusion hepatitis present formidable obstacles.

(3) The present reporting system identifies only overt cases that come to a physician's attention and are correctly diagnosed. It is well recognized that these overt cases of posttransfusion hepatitis are a very small proportion of the total posttransfusion hepatitis problem. In order to obtain maximum incidence rates, it would be necessary for all blood banks to evaluate recipients prospectively after transfusion. The evaluation of over 2-million patients, receiving over 9-million units of blood distributed annually by more than 6,000 blood banks, would be very expensive. Therefore, although the Commissioner concurs with the desirability of maintaining records of cases of posttransfusion hepatitis, and periodically reviewing the hepatitis B antigen positive rates of blood banks, these procedures contribute more as performance measurements of testing proficiency and to ascertaining hepatitis rates than they do to pedigreeing (biologically testing) donor populations to ensure the safety of collected blood.

For these reasons, the Commissioner is not now prepared to extablish procedures for all blood banks. The Bureau will review circulars and other materials in which blood banks describe their procedures to monitor the safety of paid donor blood.

17. Four comments criticized as factually arbitrary and legally improper the implication of the proposed labeling that paid blood is inherently stigmatized as a health risk since FDA has not provided mechanisms by which a commercial or hospital blood bank that pays donors yet supplies low-risk blood can avoid such a stigma. The comments characterized the labeling as unprecedented because it allows two classes of products to be licensed—one good and one bad—and therefore is inconsistent with FDA policy as applied to other classes of drugs and violates FDA's statutory mandate.

The Commissioner disagrees with the comments. A stigma is a mark of disgrace, which this regulation does not affix either to the product or to its producers merely by identifying the source of the product.

Whole blood and its components carry an undefined but documented risk of hepatitis, and this risk is known to be increased in paid donors. Each unit of blood donated, with or without monetary compensation, must have been collected in compliance with such legal provisions as the blood GMP's. The risks of using it may vary depending upon the donor who, if acceptable by medical criteria, is now considered suitable. Every drug approved by FDA has known side-effects and almost all drugs have acceptable ranges of characteristics, the recognition of which is not inconsistent with FDA's public charge.

18. One comment suggested that labeling blood or components according to donor classification will neither add to the awareness that paid donor blood carries a higher risk of transmitting hepatitis nor decrease the demand for blood from paid donors. For example, hospital administrators are aware of the use of paid donors when they contract with proprietary blood banks to meet hospital needs.

The Commissioner believes that the donor classification labeling is one of several means to increase physician awareness that blood from paid donors statistically carries a higher risk and is a major source of information for patients. The Commissioner recognizes that the demand for blood from paid donors may not immediately decrease but the data discussed in item 11 of this preamble strongly suggest that a marked impact will occur in a relatively short time. While hospital administrators or purchasing agents must regularly consider blood source, the labeling requirement may encourage physicians and users to review this matter more closely. Accordingly, the comment is rejected.

EFFECT OF LABELING ON SUPPLY AND COST

19. Seven comments suggested that the proposed rules, if adopted, would make it more difficult to maintain adequate supplies of blood. This concern is based on the following assertions: (1) the 1973 Illinois blood labeling law forced that State to import volunteer blood while sending paid blood collected in Illinois to other States, (2) the General Accounting Office has reported (MWD-82) that the proposed labeling "could cause blood shortages," and (3) in Los Angeles, Calif., where a similar blood labeling law is in effect, hospitals in affluent areas meet their needs exclusively with volunteer blood, at the expense of hospitals serving areas of lower socio-economic status, which are forced to rely heavily on blood from less desirable sources. The comments postulated that in the absence of sufficient voluntary blood to replace the paid blood sources, hospitals will be faced with critical blood shortages and not be able to meet the total blood needs of

the disadvantaged sections of society they serve. Conversely, 11 comments suggested the proposed labeling will not increase the cost of blood or create blood shortages because (1) similar programs by the American Red Cross in collaboration with blood banks have operated successfully, (2) similar labeling laws in Illinois, California, and Georgia have not created blood shortages and have quickly eliminated the use of blood that is most likely to cause hepatitis, and (3) any impact on cost or supply will be negligible compared to potential benefits.

The Commissioner reiterates his belief, stated in the preamble of the November proposal, that the proposed labeling requirement will not interrupt blood services now provided and will help to achieve the National Blood Policy objective to encourage, foster, and support efforts to establish an all-voluntary blood donation system.

The Commissioner emphasizes that the proposed donor classification labeling does not prohibit monetary payment for blood donation. Indeed, monetary payment to selected donors, especially those with rare blood groups or with a long history of blood donation without adverse posttransfusion reactions in recipients, is expected to continue as long as the need exists.

Donor classification legislation is now effective in the states of Illinois, California, Florida, and Georgia. The longest experience with such legislation, in Illinois, does not support the contention that shortages in the blood supply will result because of the donor classification requirement. Indeed, the number of units collected from voluntary donors in Illinois increased sufficiently after the enactment of the donor classification legislation to provide adequately for all needs for blood within the State.

The cost-to-benefit balance of this regulation seems beyond serious question. For example, in one Illinois hospital where carefully monitored studies were conducted, the number of cases of posttransfusion hepatitis decreased significantly following the change from the use of predominantly paid donor blood to volunteer donor blood.

The Commissioner is not aware of any data, nor were any presented by the comments, to substantiate the speculations made by the comments concerning the blood use experiences in Illinois and Los Angeles, California. Accordingly, the comments are rejected.

20. Seventeen comments suggested that the proposed labeling requirements are inflationary because (1) an additional label must be applied to the millions of units collected from volunteer blood donors, (2) physicians who use blood from paid donors will need to increase their medical malpractice insurance premiums, (3) additional expenses will be required to mount effective recruitment efforts to replace the paid donor, and (4) the demand for volunteer blood will increase, raising the price and making it available only to people who can afford to pay more for it.

As stated repeatedly, the costs will be minimal because the information will be included on labels, along with the currently required information, by various means. It is not necessary to use an additional label. The Commissioner notes that the American Red Cross, which collects from volunteer donors approximately one-half of the blood supply in this country, already uses labels that identify the donor as a volunteer.

The Commissioner is not aware of any data, nor were any presented to substantiate the contention made in the comments, that (1) physicians' malpractice insurance will increase, (2) the labeling requirements will create ongoing expenses associated with mounting recruitment efforts used to motivate donors to donate blood, and (3) the price of volunteer donor blood will increase because of the demand for it. More importantly, this argument fails to consider the human and economic costs of blood recipients contracting hepatitis from blood transfusion. Even if the required labeling results in small increased expenses for the blood facility, these costs are exceeded by the benefits of reduced morbidity and mortality from posttransfusion hepatitis.

As the Commissioner noted in the proposed regulations, the inflationary aspect of the labeling requirements has been thoroughly considered, and no inflationary impact was noted. Accordingly, the comments are rejected.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201, 501, 502, 52 Stat. 1040-1042 as amended, 1049-1051 as amended (21 U.S.C. 321, 351, 352)) and the Public Health Service Act (secs. 351, 361, 58 Stat. 702-703 as amended (42 U.S.C. 262, 264)) and under authority delegated to him (21 CFR 5.1), the Commissioner is amending Chapter I of Title 21 of the Code of Federal Regulations as follows:

1. In Part 606 by amending § 606.120 by redesignating existing paragraphs (b)(2) through (b)(13) as paragraphs (b)(3) through (b)(14), and adding a new paragraph (b)(2) to read as follows:

§ 606.120 Labeling.

* * * * *

(b) * * *

(2) The appropriate donor classification statement, "paid donor," or "volunteer donor," in no less prominence than the proper name of the product (except that these requirements shall not apply to Source Plasma (Human) or plasma derivatives).

(i) A paid donor is a person who receives monetary payment for a blood donation.

(ii) A volunteer donor is a person who does not receive monetary payment for a blood donation.

(iii) Benefits, such as time off from work, membership in blood assurance programs, and cancellation of nonreplacement fees that are not readily convertible to cash, do not constitute monetary payment within the meaning of this paragraph (b)(2).

* * * * *

2. In Part 640:

a. By revising § 640.2(f)(3) to read as follows:

§ 640.2 General requirements.

* * * * *

(f) * * * (3) the label of each container of such blood bears the information required by § 640.7(f), * * *.

b. By amending § 640.7 by revising the introductory paragraph, by redesignating existing paragraphs (a) through (f) as paragraphs (b) through (g), respectively, and by adding a new paragraph (a), and revising the redesignated paragraph (f) to read as follows:

§ 640.7 Labeling.

In addition to all other applicable labeling requirements, the following, except as prescribed in paragraphs (f) and (g) of this section, shall appear on the label of each container:

(a) *Donor classification.* The appropriate donor classification statement prescribed in § 606.120(b)(2) of this chapter.

* * * * *

(f) *Issue prior to determination of test results.* The label on each container of blood that is issued pursuant to the provisions of § 640.2(f) shall bear the following information and instructions in lieu of the information specified in paragraphs (c), (d), and (e) of this section.

* * * * *

c. By amending § 640.18 by revising paragraph (a) to read as follows:

§ 640.18 Labeling.

* * * * *

(a) The information required by § 640.7 (a), (b)(2), (c), and (d) for Whole Blood (Human), except the proper name.

* * * * *

d. By amending § 640.26 by redesignating existing paragraphs (b) through (n) as paragraphs (c) through (o), respectively, and by adding a new paragraph (b) to read as follows:

§ 640.26 **Labeling.**

* * * * *

(b) The appropriate donor classification statement prescribed in § 606.120(b)(2) of this chapter.

* * * * *

e. By amending § 640.35 by redesignating existing paragraphs (b) through (r) as paragraphs (c) through (s), respectively, and by adding a new paragraph (b) to read as follows:

§ 640.35 **Labeling.**

* * * * *

(b) The appropriate donor classification statement prescribed in § 606.120(b)(2) of this chapter.

* * * * *

f. By amending § 640.57 by redesignating existing paragraphs (b) through (o) as paragraphs (c) through (p), respectively, and adding a new paragraph (b) to read as follows:

§ 640.57 **Labeling.**

* * * * *

(b) The appropriate donor classification statement prescribed in § 606.120(b)(2) of this chapter.

* * * * *

Effective date: This regulation becomes effective May 15, 1978.

(Secs. 201, 501, 502, Pub. L. 717, 52 Stat. 1040-1042 as amended, 1049-1051 as amended (21 U.S.C. 321, 351, 352); secs. 351, 361, Pub. L. 410, 58 Stat. 702 as amended, 703 as amended (42 U.S.C. 262, 264).)

Dated: January 6, 1978.

DONALD KENNEDY,
Commissioner of Food and Drugs.

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