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State/Territory Name: IA

State Plan Amendment (SPA) #: 16-0010

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) Summary Form (with 179-like data)
- 3) Approved SPA Pages

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
601 East 12th Street, Suite 355
Kansas City, Missouri 64106



Division of Medicaid and Children's Health Operations

August 31, 2016

Charles M. Palmer, Director
Department of Human Services
Hoover State Office Building
1305 East Walnut Street, 5th Floor
Des Moines, IA 50319-0114

Dear Mr. Palmer:

On June 14, 2016, the Centers for Medicare & Medicaid Services (CMS) received Iowa's State Plan Amendment (SPA) transmittal #16-0010, with a proposed effective date of April 1, 2016. This SPA is requesting approval to update the policies regarding coverage of organ and tissue transplant services. In addition, this SPA also seeks approval to remove outdated references to the "Iowa Foundation for Medical Care" and replacing those terms with the "IME Medical Services Unit".

This SPA 16-0010 was approved on August 26, 2016, with an effective date of April 1, 2016, as requested by the state. Enclosed is a copy of the CMS-179 Form, as well as, the approved pages for incorporation into the Iowa State plan.

If you have any questions regarding this amendment, please contact Gail Brown at (816) 426-5925 or Gail.Brown@cms.hhs.gov

Sincerely,

8/31/2016

James G. Scott
Associate Regional Administrator
for Medicaid and Children's Health Operations

Signed by: James G. Scott -A

Enclosure

cc:
Mikki Stier, Medicaid Director
Jennifer Steenblock, IME
Marty Swartz, IME
Alisa Horn, IME

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES		1. TRANSMITTAL NUMBER <div style="text-align: center;">1 6 — 0 1 0</div>	2. STATE <div style="text-align: center;">IOWA</div>
		3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
TO: REGIONAL ADMINISTRATOR CENTERS FOR MEDICARE & MEDICAID SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES		4. PROPOSED EFFECTIVE DATE <div style="text-align: right;">April 1, 2016</div>	
5. TYPE OF PLAN MATERIAL (Check One)			
<input type="checkbox"/> NEW STATE PLAN <input type="checkbox"/> AMENDMENT TO BE CONSIDERED AS NEW PLAN <input checked="" type="checkbox"/> AMENDMENT			
COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (Separate transmittal for each amendment)			
6. FEDERAL STATUTE/REGULATION CITATION <div style="text-align: center;">42 CFR 441.35: Organ Transplants</div>		7. FEDERAL BUDGET IMPACT a. FFY 2016 \$ 0 b. FFY 2017 \$ 0	
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT <div style="text-align: center;">Attachment 3.1-E, Pages 1, 2</div>		9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable) <div style="text-align: center;">Attachment 3.1-E, Pages 1, 2</div>	
10. SUBJECT OF AMENDMENT <div style="text-align: center;">Updates policies regarding coverage of organ & tissue transplant services. Also removes outdated references to the Iowa Foundation for Medical Care and replaces with the IME Medical Services Unit.</div>			
11. GOVERNOR'S REVIEW (Check One)			
<input checked="" type="checkbox"/> GOVERNOR'S OFFICE REPORTED NO COMMENT <input type="checkbox"/> OTHER, AS SPECIFIED <input type="checkbox"/> COMMENTS OF GOVERNOR'S OFFICE ENCLOSED <input type="checkbox"/> NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL			
12. SIGNATURE OF STATE AGENCY OFFICIAL <div style="text-align: center;">[Signature]</div>		16. RETURN TO CHARLES M. PALMER DIRECTOR DEPARTMENT OF HUMAN SERVICES 1305 EAST WALNUT 5TH FLOOR DES MOINES IA 50319-0114	
13. TYPED NAME <div style="text-align: center;">CHARLES M. PALMER</div>			
14. TITLE <div style="text-align: center;">DIRECTOR</div>			
15. DATE SUBMITTED <div style="text-align: center;">6-13-16</div>			
FOR REGIONAL OFFICE USE ONLY			
17. DATE RECEIVED <div style="text-align: center;">June 13, 2016</div>		18. DATE APPROVED <div style="text-align: center;">August 26, 2016</div>	
PLAN APPROVED - ONE COPY ATTACHED			
19. EFFECTIVE DATE OF APPROVED MATERIAL <div style="text-align: center;">April 1, 2016</div>		20. SIGNATURE OF REGIONAL OFFICIAL <div style="text-align: center;">/s/</div>	
21. TYPED NAME <div style="text-align: center;">James G Scott</div>		22. TITLE <div style="text-align: center;">Associate Regional Administrator for Division of Medicaid and Children's Health Operations</div>	
23. REMARKS			

STANDARDS FOR THE COVERAGE OF ORGAN TRANSPLANT SERVICES

Payment will be made only for the following organ and tissue transplant services:

- Kidney, cornea, skin, and bone transplants.
- Allogeneic stem cell transplants for the treatment of aplastic anemia, severe combined immunodeficiency disease (SCID), Wiskott-Aldrich syndrome, follicular lymphoma, Fanconi anemia, paroxysmal nocturnal hemoglobinuria, pure red cell aplasia, amegakaryocytosis/congenital thrombocytopenia, beta thalassemia major, sickle cell disease, Hurler's syndrome (mucopolysaccharidosis type 1 [MPS-1]), adrenoleukodystrophy, metachromatic leukodystrophy, refractory anemia, agnogenic myeloid metaplasia (myelofibrosis), familial erythrophagocytic lymphohistiocytosis and other histiocytic disorders, acute myelofibrosis, Diamond-Blackfan anemia, epidermolysis bullosa, or the following types of leukemia: acute myelocytic leukemia, chronic myelogenous leukemia, juvenile myelomonocytic leukemia, chronic myelomonocytic leukemia, acute myelogenous leukemia, and acute lymphocytic leukemia.
- Autologous stem cell transplants for treatment of the following conditions: acute leukemia; chronic lymphocytic leukemia; plasma cell leukemia; non-Hodgkin's lymphomas; Hodgkin's lymphoma; relapsed Hodgkin's lymphoma; lymphomas presenting poor prognostic features; follicular lymphoma; neuroblastoma; medulloblastoma; advanced Hodgkin's disease; primitive neuroendocrine tumor (PNET); atypical/rhabdoid tumor (ATRT); Wilms' tumor; Ewing's sarcoma; metastatic germ cell tumor; or multiple myeloma.
- Liver transplants for persons with extrahepatic biliary atresia or any other form of end-stage liver disease, except that coverage is not provided for people with a malignancy extending beyond the margins of the liver.

Liver transplants require preprocedure review by the IME medical services unit. Covered liver transplants are payable only when performed in a facility which meets the requirements set forth by the Department.

- Heart transplants for persons with inoperable congenital heart defects, heart failure, or related conditions. Artificial hearts and ventricular assist devices as a temporary life-support system until a human heart becomes available for transplants are covered. Artificial hearts and ventricular assist devices as a permanent replacement for a human heart are not covered. Heart-lung transplants are covered where bilateral or unilateral lung transplantation with repair of a congenital cardiac defect is contraindicated.

Heart transplants, heart-lung transplants, artificial hearts, and ventricular assist devices described above require preprocedure review by the IME medical services unit. Covered heart transplants are payable only when performed in a facility which meets the requirements set forth by the Department.

- Lung transplants for persons having end-stage pulmonary disease. Lung transplants require preprocedure review by the IME medical services unit. Covered transplants are payable only when performed in a facility which meets Department requirements. Heart-lung transplants are covered consistent with coverage criteria for heart transplants, as stated above.
- Pancreas transplants for people with type I diabetes mellitus, as follows:
 - Simultaneous pancreas-kidney (SPK) transplants and pancreas after kidney (PAK) transplants are covered.
 - Pancreas transplants alone (PTA) are covered for persons exhibiting any of the following:
 - A history of frequent, acute, and severe metabolic complications (e.g., hypoglycemia, hyperglycemia, or ketoacidosis) requiring medical attention.
 - Clinical problems with exogenous insulin therapy that are so severe as to be incapacitating.
 - Consistent failure of insulin-based management to prevent acute complications.

The pancreas transplants listed above require preprocedure review by the IME medical services unit. Covered transplants are payable only when performed in a facility which meets Department requirements. Transplantation of islet cells or partial pancreatic tissue is not covered.

All transplants must be medically necessary and meet other general requirements for physician and hospital services. No payment is made for any transplant not specifically listed above.

Donor expenses incurred directly in connection with a covered transplant are payable. Expenses incurred for complications that arise with respect to the donor are covered only if they are directly and immediately attributed to surgery. Expenses of searching for a donor are not covered.

The facility criteria in place for heart, liver, lung, and pancreas transplant centers are consistent with the accessibility of high quality care to recipients eligible for the procedures under this plan. Criteria for recipient selection and education, staffing and resource commitment,, experience and survival rates, organ procurement, maintenance of data, research, review and evaluation, and application procedures may be found under 441 Iowa Administrative Code 78.3(10).