

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF DIRECTOR

ACTION REFERRAL

TO	DATE
<i>Medical Services/Hubler</i>	<i>2-15-11</i>

DIRECTOR'S USE ONLY	ACTION REQUESTED
1. LOG NUMBER <div style="text-align: center; font-size: 1.2em;"><i>001357</i></div>	<input type="checkbox"/> I Prepare reply for the Director's signature DATE DUE _____
2. DATE SIGNED BY DIRECTOR <div style="text-align: center; font-size: 1.2em;"><i>CC: Mr. Keck, Deps, CMS file</i></div> <div style="text-align: center; font-size: 3em; color: red;"><i>✓</i></div>	<input type="checkbox"/> I Prepare reply for appropriate signature DATE DUE _____ <input type="checkbox"/> I FOIA DATE DUE _____ <input checked="" type="checkbox"/> Necessary Action

APPROVALS <small>(Only when prepared for director's signature)</small>	APPROVE	* DISAPPROVE <small>(Note reason for disapproval and return to preparer.)</small>	COMMENT
1.			
2.			
3.			
4.			

Department of Health & Human Services
Centers for Medicare & Medicaid Services
61 Forsyth St., Suite 4T20
Atlanta, Georgia 30303-8909



February 3, 2011

RECEIVED

Mr. Anthony E. Keck, Director
Department of Health and Human Services
P.O. Box 8206
Columbia, South Carolina 29202-8206

Department of Health & Human Services
OFFICE OF THE DIRECTOR

Dear Mr. Keck:

This formal Request for Additional Information (RAI) is in response to your request to amend South Carolina's Home and Community Based Waiver for Children with Pervasive Developmental Disorders. Our review of the request (control #0456.R01.01) found that it did not conform fully to statutory and regulatory requirements. Please provide the clarification necessary to respond to the following issues:

Main Module 1. Requested Information, Item H

The State did not specify whether the waiver provides services to individuals who are eligible for both Medicare and Medicaid. The State should check item H, if the waiver covers dual-eligibles.

Appendix G-1-d: Review of and Response to Critical Events or Incidents

While the State addresses the 24-hour timeline for reporting critical events and incidents, the State refers CMS to DDSN Directives 100-09-DD and 534-02-DD for the timelines for completing investigations of critical events. Please include the pertinent information from the DDSN Directives in the waiver application. Also, in our review of the DDSN Directives, CMS was unable to find timelines for investigating reports of a less critical nature. Please explain how less critical incidents are handled to ensure all complaints/reports are investigated with a report of findings in a timely manner.

Appendix G-2-c-i: Participant Safeguard Concerning Restraints and Restrictive Interventions

Concerning the use of restraints, please specify and provide additional detail regarding;

- 1) What methods are used for detecting unauthorized use or inappropriate use of restraints or seclusion?
- 2) Are these being reported as part of the statewide trend data to DHHS?
- 3) What are the training requirements for staff using restraints?

Mr. Anthony E. Keck
February 3, 2011
Page 2

Appendix G-2-e-ii: State Oversight Responsibility

Concerning the use of restraints, please specify and provide additional detail regarding:

1. How data are analyzed to identify trends and patterns and support improvement strategies.
2. The methods for overseeing the operation of the incident management system including how data are collected, compiled and used to prevent re-occurrence, and
3. The frequency of oversight activities.

Appendix G-3-e: Medication Administration by Waiver Providers

The State indicates, "... DDSN recommends that all providers utilize an established Medication Technician Certification program." Please clearly specify the training/education requirements that non-medical waiver providers **must** have in order to administer medications to participants who cannot self-administer and the extent of the oversight of these personnel by licensed medical professionals.

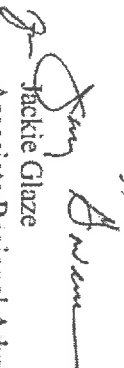
Appendix G-3-e-iii: Medication Error Reporting

The State indicates, "Providers responsible for medication administration are required to record medication errors but make information about medication errors available only when requested by the State." How often does the State request and/or review all data related to medication error reporting?

Under section 1915(f) of the Social Security Act, a waiver request must be approved, denied or additional information requested within 90 days of receipt or the request will be deemed approved. The 90-day review period on this request ends February 17, 2011. This request for additional information will, however, stop the 90-day clock. Once the additional information is submitted to us, the 90-day review clock will restart at day one.

If you have any questions relating to this request, please contact Connie Martin at (404) 562-7412.

Sincerely,



Jackie Glaze
Associate Regional Administrator
Division of Medicaid & Children's Health Operations

Department of Health & Human Services
Centers for Medicare & Medicaid Services
61 Forsyth St., Suite 4T20
Atlanta, Georgia 30303-8909



February 3, 2011

RECEIVED

Mr. Anthony E. Keck, Director

FEB 17 2011

Department of Health and Human Services

P.O. Box 8206

Columbia, South Carolina 29202-8206

Department of Health & Human Services
OFFICE OF THE DIRECTOR

Dear Mr. Keck:

This formal Request for Additional Information (RAI) is in response to your request to amend South Carolina's Home and Community Based Waiver for Children with Pervasive Developmental Disorders. Our review of the request (control #0456.R01.01) found that it did not conform fully to statutory and regulatory requirements. Please provide the clarification necessary to respond to the following issues:

Main Module, 1. Requested Information, Item H

The State did not specify whether the waiver provides services to individuals who are eligible for both Medicare and Medicaid. The State should check item H, if the waiver covers dual-eligibles.

Appendix G-1-d: Review of and Response to Critical Events or Incidents

While the State addresses the 24-hour timeline for reporting critical events and incidents, the State refers CMS to DDSN Directives 100-09-DD and 534-02-DD for the timelines for completing investigations of critical events. Please include the pertinent information from the DDSN Directives in the waiver application. Also, in our review of the DDSN Directives, CMS was unable to find timelines for investigating reports of a less critical nature. Please explain how less critical incidents are handled to ensure all complaints/reports are investigated with a report of findings in a timely manner.

Appendix G-2-c-i: Participant Safeguard Concerning Restraints and Restrictive Interventions

Concerning the use of restraints, please specify and provide additional detail regarding;

- 1) What methods are used for detecting unauthorized use or inappropriate use of restraints or seclusion?
- 2) Are these being reported as part of the statewide trend data to DHHS?
- 3) What are the training requirements for staff using restraints?

Mr. Anthony E. Keck
February 3, 2011

Page 2

Appendix G-2-c-ii: State Oversight Responsibility

Concerning the use of restraints, please specify and provide additional detail regarding;

1. How data are analyzed to identify trends and patterns and support improvement strategies,
2. The methods for overseeing the operation of the incident management system including how data are collected, compiled and used to prevent re-occurrence, and,
3. The frequency of oversight activities.

Appendix G-3-c: Medication Administration by Waiver Providers

The State indicates, "... DDSN recommends that all providers utilize an established Medication Technician Certification program." Please clearly specify the training/education requirements that non-medical waiver providers **must** have in order to administer medications to participants who cannot self-administer and the extent of the oversight of these personnel by licensed medical professionals.

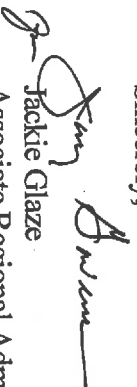
Appendix G-3-c-iii: Medication Error Reporting

The State indicates, "Providers responsible for medication administration are required to record medication errors but make information about medication errors available only when requested by the State." How often does the State request and/or review all data related to medication error reporting?

Under section 1915(f) of the Social Security Act, a waiver request must be approved, denied or additional information requested within 90 days of receipt or the request will be deemed approved. The 90-day review period on this request ends February 17, 2011. This request for additional information will, however, stop the 90-day clock. Once the additional information is submitted to us, the 90-day review clock will restart at day one.

If you have any questions relating to this request, please contact Connie Martin at (404) 562-7412.

Sincerely,



Jackie Glaze
Associate Regional Administrator
Division of Medicaid & Children's Health Operations