

MEMORANDUM

Texas Department of Human Services * Long Term Care/Policy

TO: LTC-R Regional Directors
Home and Community Support Services Agencies (HCSSA) Program Administrators

FROM: Marc Gold
Section Manager
Long Term Care-Policy
State Office MC: W-519

SUBJECT: Regional Survey & Certification Letter #00-08

DATE: July 7, 2000

The attached RS&C Letter is being provided to you for information purposes and should be shared with all professional staff.

- RS&C Letter No. 00-08 - OSCAR PROGRAMMING RELEASE; Call Dee Sandefur, Professional Services, at (512) 438-2631.

If you have any questions, please direct inquiries to the individuals or sections listed above.

~Original Signature on File~

Marc Gold

Attachment

DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Care Financing Administration
Division of Medicaid and State Operations, Region VI

1301 Young Street, Room 833
Dallas, Texas 75202
Phone (214) 767-6301
Fax (214) 767-0270

March 28, 2000

REGIONAL SURVEY AND CERTIFICATION LETTER NO: 00-08

To: All State Survey Agencies (Information)
All Title XIX Single State Agencies (Information)

Subject: OSCAR PROGRAMMING RELEASE -- PLANNED IMPLEMENTATION DATE:
EARLY May, 2000

We want to take this opportunity to inform you about the changes we are working on in the OSCAR system (CLIA and non-CLIA) for the next major programming release, which is tentatively scheduled for implementation during the first weekend in May.

Note: We will send a more detailed note closer to the actual release date.

Non-CLIA changes

1. Add an edit for Hospice field PH9 (Physician Services) to allow for entry of Under Arrangement code '2', based on the regulatory change.
2. Add a new field to ODIE C&T screen for SNF and NF to identify a FOSS survey. This field would also be available in the OSCAR user defined reports so that FOSS survey characteristics can be compared against non-FOSS surveys.
3. Add 2 new fields to ODIE 671 screen for SNF and NF only which will identify the date an independent dispute resolution (IDR) meeting was requested, and the date the IDR was completed. The same fields will be added to the COMP system.
4. For the Hospice category (code 16), allow entry of an accredited indicator on N.1 ODIE (C&T screen).
5. Create a new OSCAR standard report for SNFs and NFs that computes the number of months between standard health surveys for purposes of determining statewide averages.

CLIA Changes

1. Allowing Gaps in Certificates

This release will give the States and regions the ability to reactivate a laboratory, either with or without a gap, if the termination date is within 6 months of today's date. If reactivating a laboratory that has been terminated longer than 6 months, a gap in certificate will be mandatory. This change

will remedy two long-standing problems: 1) of billing a laboratory retroactively to pay for certificates that were not warranted and were never issued, or, 2) of issuing a second CLIA number to the same laboratory.

With this change, you and your States must understand how important it is to enter accurate termination dates. After a laboratory reaches the 6-month 'window', i.e., the termination date is more than 6 months from today's date, the CLIA program will audit off the laboratory's billing and accounting records. If you or the State reactivates the CLIA number, then the laboratory will be processed as an initial certification.

2. Processing Changes in CLIA Exempt Status (Washington and New York only)

For those States that are CLIA exempt, this release will allow a laboratory to move in and out of exemption status. Currently, these status changes must be processed manually by our programmers.

3. Establishing an Accounts Receivable System

In order to conform with the generally accepted accounting principles, modifications will be made to the CLIA billing system to create a standard accounts receivable module and to develop revenue accounts. Using the accounts receivable date, the CLIA program will have a better image of the funds owed to the program.

Note: The development of the accounts receivable system will not change CLIA's billing and rebilling process that is currently in place.

4. Modify EIN edits

When processing refunds, the Employer Identification Number (EIN) is key information that must be correct. The Department of the Treasury will not longer process CLIA refunds if the EIN appears bogus. For this reason, we are strengthening the online edits to prevent the entry of discrepant numbers such as, all 0's or 1's, etc.

5. Develop Upload Capability for Accreditation Organizations

With the next release, we will have available to CAP and COLA the ability to upload their files to HCFA that contains verification (match) and specialty information. The other accreditation organizations, JCAHO, ASHI, AABB, and AOA, are already able to enter the verification, specialty, and test volume information directly into the CLIA and ODIE data bases.

6. Issuing Page 2 of the Certificate of Accreditation (COA)

Using the test volume and specialty information supplied to us by the accreditation organizations, we will be able to send the laboratory's COA fees based on this more current information. In addition, we will begin printing the specialty information on the second page of the Certificate of Accreditation, which is issued after a laboratory pays its COA fees.

7. New or Revised OSCAR Reports

- a. *OSCAR Report 74 (New)* -- identifies any laboratory that changed its accreditation status, i.e., no longer affiliated with accreditation organization, accreditation status not confirmed, etc., as reported by the accreditation organizations and recorded in the Accredited Remarks fields located on CLIA N.2
- b. *OSCAR Report 75 (New)* -- identifies any laboratory not matched (not verified) by the accreditation organizations as indicated on the HCFA-116. (This report is a 'print' version of the file that the accreditation organization download via OSCAR Report 98.)
- c. *OSCAR Report 76 (New)* -- identifies any laboratory that was matched (verified) by one (or more) accreditation organizations. (This report is a 'print' version of the file that the accreditation organization downloads via OSCAR Report 99.)
- d. *OSCAR 77 (New)* -- computes the average number of hours needed to survey laboratories, broken out by certificate schedule code. Only surveys (standard and/or revisits) with onsite hours present are included in the computations.
- e. *OSCAR Report 88 (CLIA Paid Terminated Labs)* -- corrects a problem in the selection criteria that only looked at a laboratory's payment status for the current certificate, rather than also looking at the laboratory's pending certificate and its payment status.
- f. *OSCAR Report 91 (MSA DATA Extract)* -- modifies the selection criteria for this report to include only those laboratories with updates that directly affect the CLIA certificate information made available to the Medicaid State Agencies. This change will reduce the overall volume of records to be downloaded by the Mass.
- g. *OSCAR 153S (New)* -- computes the number of laboratories that failed two consecutive PT events, or 2 out of 3 events, broken out by State and region. (This report summarizes the detailed information available in OSCAR Report 153.)

CLIA -- Accreditation Workflow Procedures

With this release, we have completed programming a data exchange process involving the collection of pertinent CLIA information between HCFA and the 6 accreditation organizations. Since there are many steps involved in collecting data on accredited laboratories, we attempted to spell out this process to make it more understandable to all the entities involved (States, the regions, the accreditation organizations, HCFA CO).

Attached are DRAFT accreditation workflow procedures that describe the so-called 'life cycle' of an accredited laboratory -- from the time a laboratory applies for a CLIA certificate to the time it receives its Certificate of Accreditation and is billed for its renewal fees. We tried to outline the actions that each entity needs to take to keep the workflow process moving and to ensure that the information is received timely and accurately. Also described are the variations involved in processing certificate status changes for laboratories changing TO a certificate of accreditation as well as those changing FROM a certificate of accreditation.

If you have the time, we would welcome your comments on these procedures, focusing on these questions:

- Are the workflow procedures helpful to you?

- Can you suggest any changes?
- Do you like the information conveyed via table form, or narrative form, or both?

(We also sent these DRAFT procedures to the accreditation organizations for their review and comments.)

If you have any questions regarding this note, please E-mail LaDonna Fulton at (lfulton@hcfa.gov) or call 214-767-4417.

Sincerely,

~Signature on File~

Molly Crawshaw, Chief
Survey and Certification Operations Branch
Division of Medicaid and State Operations

Enclosure

LIFE CYCLE FOR A CERTIFICATE OF ACCREDITATION

- Laboratory contacts the accreditation organization and notifies of its intent to be accredited by them for CLIA purposes.
- Laboratory completes the HCFA-116 and sends it to its State agency for data entry. The laboratory must indicate on the HCFA-116 which accreditation organization it wishes to be accredited by.
- The State agency enters the HCFA-116 into the CLIA system. The effective date is generated to be equal to the date the HCFA-116 is accepted into the CLIA data system. The CLIA system sends the laboratory its registration certificate fee.
- The CLIA system issues a registration certificate that is valid for two years from the effective date once the laboratory pays the fee in full. At that point, the laboratory's information is available to the accreditation organizations for downloading via Report 98 (Unmatched lab file). It is also available to the States and Regions for monitoring purposes via Report 75 (unmatched labs, hard copy report).
- The accreditation organization sends a verification 'match' to HCFA via direct data entry or upload process once it has surveyed the laboratory and found it in compliance with its requirements. Until the upload process is in place, match information is manually entered by the organization's HCFA contact. The laboratory's information is now available to the accreditation organization for downloading via Report 99 (Matched lab file) and to the States and Regions for monitoring purposes via Report 76 (Matched labs, hard copy report).
- The CLIA system generates the validation and certificate of accreditation fees. After full payment is received in the CLIA system, the laboratory is mailed its certificate of accreditation. (The effective date of the certificate of accreditation is equal to the match date in the CLIA system.)
- Six months prior to the expiration of the current certificate of accreditation, the CLIA system sends the laboratory its renewal validation and certificate of accreditation fees. Once full payment is received in the CLIA system, and it is 30 days prior to the expiration of the current certificate,, the laboratory is mailed its next certificate of accreditation.

Processes by which status changes to a certificate of accreditation are processed

1. Laboratory has applied for a certificate of compliance, is currently in registration certificate status, and requests a change to a certificate of accreditation:

- Laboratory notifies accreditation organization of intent to be accredited by them for CLIA purposes.
- Laboratory notifies State agency of intent to become a certificate of accreditation.
- State agency enters the status change into the CLIA system. The new effective date is system generated to be equal to the current registration certificate effective date (**the lab stays within the same 2-year registration certificate and is not mailed a new registration certificate**).
- The laboratory follows the life cycle for a certificate of accreditation at the point where the laboratory has been mailed its registration certificate.

2. Laboratory has a current certificate of compliance and requests a change to a certificate of accreditation:

- Laboratory notifies accreditation organization of intent to be accredited by them for CLIA purposes.
- Laboratory notifies State agency of intent to become a certificate of accreditation.
- State agency enters the status change into the CLIA system. The new effective date may be within the current certificate time period or the day after it expires.
- The CLIA system processes the status change 6 months prior to the new effective date, or immediately if within 6 months.
- The CLIA system bills the laboratory for the registration certificate. (If the lab has paid a compliance fee and the survey is not done by HCFA, that money is applied towards the registration certificate and certificate of accreditation and validation fees. Any monies left over are refunded to the laboratory.)
- The CLIA system sends the registration certificate to the laboratory when fully paid and within 30 days of the effective date.
- The laboratory follows the life cycle for a certificate of accreditation at the point where the laboratory has been mailed its registration certificate.

3. Lab has a current certificate of waiver or provider-performed microscopy and requests a change to a certificate of accreditation:

- Laboratory notifies accreditation organization of intent to be accredited by them for CLIA purposes.
- Laboratory notifies State agency of intent to become a certificate of accreditation.
- State agency enters the status change into the CLIA system. (The new effective date can be any date within the current certificate time period or equal to the day after it expires.)
- The CLIA system processes the status change 6 months prior to the new effective date, or immediately if less than 6 months.
- The CLIA system bills the laboratory for the registration certificate.
- The CLIA system mails the registration certificate to the laboratory when fully paid and within 30 days of the new effective date.
- The laboratory follows the life cycle for a certificate of accreditation at the point where the laboratory has been mailed its registration certificate.

Process by which status changes from a certificate of accreditation are processed

4. Laboratory has a current registration certificate for a certificate of accreditation and requests a change to a certificate of compliance:

- Laboratory notifies accreditation organization of intent to be surveyed by the State agency for CLIA purposes.
- Laboratory notifies State agency of intent to be surveyed by them for CLIA purposes.
- State agency enters the status change into the CLIA system. The new effective date is system generated equal to the current registration certificate effective date.
- The CLIA system moves the registration certificate up to pending status and sends the laboratory a bill for the compliance fee.
- Laboratory fully pays all fees and the CLIA system moves the registration certificate to current status. The laboratory remains within the same 2 year registration period and no new registration certificate is mailed.
- The laboratory follows the life cycle of a certificate of compliance at the point where the laboratory has been mailed its registration certificate.

5. Laboratory has a current certificate of accreditation and requests a change to a certificate of compliance:

- Laboratory notifies accreditation organization of intent to be surveyed by the State agency for CLIA purposes.
- Laboratory notifies State agency of intent to be surveyed by them for CLIA purposes.
- State agency enters the status change into the CLIA system. The new effective date is system generated equal to the current effective date or any day within the current certificate period or equal to the day after the current certificate expires.
- The CLIA system processes status change 6 months prior to the new effective date, or immediately if within 6 months.
- The CLIA system sends the laboratory its registration and compliance fees. Any available monies are applied to the new fee.
- Laboratory fully pays all fees and the CLIA system mails the registration certificate to the laboratory when it is within 30 days of the registration certificate effective date.
- The laboratory follows the life cycle of a certificate of compliance at the point where the laboratory has been mailed its registration certificate.

6. Laboratory has a certificate of accreditation and requests a change to a certificate of waiver or PPMP:

- Laboratory notifies accreditation organization of intent to change to a certificate of waiver or PPMP.
- Laboratory notifies State agency of intent to change to a certificate of waiver or PPMP.
- State agency enters the status change into the CLIA system. The new effective date is system generated equal to the day after the current certificate expires.
- The CLIA system processes status change 6 months prior to the new effective date, or immediately if within 6 months.
- The CLIA system sends the laboratory its certificate of waiver or PPMP fees. Any available monies are applied to the new fee.
- Laboratory fully pays all fees and the CLIA system mails the certificate of waiver or PPMP to the laboratory when it is within 30 days of the certificate effective date.
- The laboratory follows the life cycle of a certificate of waiver or PPMP at the point where the laboratory has been mailed its registration certificate.

7. **Process by which a laboratory changes accreditation organizations while remaining a certificate of accreditation:**

- Laboratory notifies its current accrediting organization of its intent to be accredited by another organization for CLIA purposes.
- Laboratory notifies new accreditation organization of its intent to be accredited by them for CLIA purposes.
- Laboratory notifies State agency of intent to change accreditation organizations.
- The State agency enters the new accrediting organization identifying information into the CLIA data system.
- The old accreditation organization enters in the CLIA system the withdrawal remarks and effective date of the change via direct data entry or upload process.
- HCFA (SA, RO, CO) monitors the process via OSCAR Reports 75 and 76.
- The new accrediting organization notifies HCFA (via direct data entry or upload) with verification of the laboratory's accreditation when the laboratory completes the accreditation process, i.e., it is in compliance with the organization's requirements.
- HCFA CO removes the verification match indicator for the old accreditation organization in the CLIA system.
- The laboratory continues its current CLIA billing cycle and remains within the same two year accreditation certificate. No new certificate of accreditation is mailed until it is time for renewal.
- Laboratory follows the life cycle of a certificate of accreditation at the point where the laboratory is sent its renewal fees.

(Once we begin to collect specialty information from the accrediting organizations and store it in the OSCAR data base, this process will be amended to incorporate responsibility for speciality verification and accuracy.)

PROCESSES BY WHICH STATUS CHANGES TO A CERTIFICATE OF ACCREDITATION ARE PROCESSED

1. Laboratory has applied for a certificate of compliance, is currently in registration certificate status, and requests a change to a certificate of accreditation:

Laboratory actions	Workflow process
Laboratory notifies the accreditation organization or its intent to be accredited by them for CLIA purposes.	
Laboratory notifies the State agency of intent to be accredited by a specified accreditation organization.	State agency enters status change into the CLIA system. (The new effective date is system generated equal to the current certificate effective date.)
	Laboratory remains within the same registration period and no new registration certificate is mailed.
	Laboratory follows the life cycle of a certificate of accreditation at the point where the laboratory receives its registration certificate.

PROCESSES BY WHICH STATUS CHANGES TO A CERTIFICATE OF ACCREDITATION ARE PROCESSED

2. Laboratory has a current certificate of compliance and requests a change of accreditation:

Laboratory actions	Workflow process
Laboratory notifies the accreditation organization of its intent to be accredited by them for CLIA purposes.	
Laboratory notifies State agency of intent to be accredited by a specified accreditation organization.	State agency enters the status change into the CLIA system. (The new effective date can be any day within the current certificate or equal to the day after the current certificate expires.)
	CLIA system processes the status change 6 months prior to the new effective date, or immediately if within 6 months.
	CLIA system bills the laboratory for a registration certificate. CLIA system applies any available monies to the new fee. Any monies left over are refunded to the laboratory.
Laboratory pays registration certificate fee in full.	CLIA system sends registration certificate to the laboratory when fully paid and within 30 days of the effective date.
	Laboratory follows the life cycle for a certificate of accreditation at the point where the laboratory has been mailed its registration certificate.

PROCESSES BY WHICH STATUS CHANGES TO A CERTIFICATE OF ACCREDITATION ARE PROCESSED

3. Laboratory has a current certificate of waiver or provider-performed microscopy and requests a change to a certificate of accreditation:

Edits	Certification process
Laboratory notifies accreditation organization of intent to be accredited by them for CLIA purposes.	
Laboratory notifies the State agency of intent to change certificate type to a certificate accreditation.	State agency enters the status change into the CLIA system. (The new effective date can be any date within the current certificate or equal to the day after the current certificate expires.)
	CLIA system processes the status change 6 months prior to the new effective date, or immediately if within 6 months.
	CLIA system bills laboratory for the registration certificate. CLIA system applies any available monies to the new fee. Any monies left over are refunded to the laboratory.
Laboratory pays registration certificate fee in full.	CLIA system sends registration certificate to the laboratory when fully paid and within 30 days of the effective date.
	Laboratory follows the life cycle for a certificate of accreditation at the point where the laboratory has been mailed its registration certificate.

PROCESSES BY WHICH STATUS CHANGES FROM A CERTIFICATE OF ACCREDITATION ARE PROCESSED

4. Laboratory has a current registration certificate for a certificate of accreditation and requests a change to a certificate of compliance:

Edits	Certification process
Laboratory notifies accreditation organization of its intent to be surveyed by the State agency for CLIA purposes	
Laboratory notifies State agency of intent to be surveyed by the State agency for CLIA purposes.	State agency enters the status change into the CLIA system. (New effective date is system generated to equal the current registration certificate effective date.)
	If the laboratory has not fully paid the compliance and registration certificate fees, the CLIA system moves the registration certificate back to pending and the laboratory is sent a bill for the outstanding fees.
Laboratory fully pays the registration and compliance fees.	If the registration certificate is pending, CLIA system moves it to current. The laboratory remains within the same registration period and no new registration certificate is mailed.
	Laboratory follows the life cycle of a certificate of compliance at the point where the laboratory has been mailed its registration certificate.

PROCESS BY WHICH STATUS CHANGES FROM A CERTIFICATE OF ACCREDITATION ARE PROCESSED

5. Laboratory has a current certificate of accreditation and requests a change to a certificate of compliance:

Edits	Certification process
Laboratory notifies accreditation organization of intent to be surveyed by State agency for CLIA purposes.	
Laboratory notifies State of intent to be surveyed by the State agency for CLIA purposes.	State agency enters the status change into the CLIA system. (New effective date can be equal to the current certificate effective date or any day within the current certificate or equal to the day after the current certificate expires.)
	CLIA system processes status change 6 months prior to the new effective date, or immediately if within 6 months.

PROCESS BY WHICH STATUS CHANGES FROM A CERTIFICATE OF ACCREDITATION ARE PROCESSED

6. Laboratory has a certificate of accreditation and requests a change to a certificate of waiver or PPMP:

Edits	Certification process
Laboratory notifies accreditation organization of intent to change certificate type to a certificate of waiver or PPMP.	
Laboratory notifies State agency of intent to change certificate type to a certificate of waiver or PPMP.	State agency enters status change into the CLIA system. (New effective date can be any date within the current certificate or equal to the day after the current certificate expires.)
	CLIA system processes the status change 6 months prior to the new effective date, or immediately if within 6 months.

PROCESS BY WHICH A LABORATORY CHANGES ACCREDITATION ORGANIZATIONS WHILE REMAINING A CERTIFICATE OF ACCREDITATION

7. Laboratory changes accreditation organizations but remains a certificate of accreditation:

Edits	Certification process
Laboratory notifies its current accreditation organization of its intent to be accredited by another organization for CLIA purposes.	
Laboratory notifies new accreditation organization of its intent to be accredited by them for CLIA purposes.	
Laboratory notifies State agency of intent to change accreditation organizations and specifies which accreditation organization it is change to.	State agency updates the CLIA system to indicate the new accreditation organization by which the laboratory will be accredited.
	New accreditation organization downloads OSCAR Report 98 (Unmatched lab file) to get the information on the laboratory.
	Old accreditation organization enters withdrawal remarks and date via direct data entry or upload process.
	HCFA (SA, RO, CO) monitors the change in accreditation organizations via OSCAR Reports 74, 75 and 76.
Laboratory completes the accreditation process with the new accreditation organization.	Accredited match with the new organization is entered either manually by HCFA CO, or manually or electronically by the new accreditation organization . The laboratory is now available to that organization via OSCAR Report 99.
	HCFA CO removes the verification match indicator from the old accreditation organization.
	Laboratory continues its current CLIA billing cycle and remains within the same certificate of

	accreditation period. No new certificate of accreditation is mailed until it is time for the laboratory to receive its renewal fee.
	Laboratory follows the life cycle of a certificate of accreditation at the point where the laboratory is sent its renewal fees.