



Center for Clinical Standards and Quality /Survey & Certification Group

Ref: S&C: 13-29-Transplant

DATE: May 10, 2013

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Delayed Publication of Scientific Registry for Transplant Recipients (SRTR) Program Specific Reports (PSR) and Implications for Centers for Medicare & Medicaid Services (CMS) Transplant Program Oversight

Memorandum Summary

- **Delay in Outcomes Information** –The release of the January 2013 SRTR PSRs has been delayed while CMS works with the Social Security Administration (SSA) and the Health Resources and Services Administration (HRSA) to address changes to the availability of the Social Security Master Death File (SSMDF) data, which is used in calculating the PSR reports. Medicare regulations require that CMS use the most recent SRTR report for determining compliance with Medicare outcome requirements. As such, the July 2012 SRTR PSRs will be used to determine compliance until further notice.
- **Programs with Condition-level deficiencies may apply for mitigating factors (MF) to avoid termination** - Transplant programs that were not in compliance according to the July 2012 SRTR PSRs, may apply for consideration of MF prior to their prospective Medicare termination date. As part of the MF process, we examine the most recent data available to us and the transplant program, including data that may not yet be published in the PSRs.

Background

Medicare regulations require that programs meet certain thresholds for patient and graft survival 1-year post transplant. The regulation requires that this determination be based on the *most recent* SRTR PSR. Specifically, the PSRs report post-transplant patient and graft survival using complex, risk-adjusted computations, to calculate program specific expected levels for patient and graft survival. These computations include information from the SSMDF, which reports all individuals who may have died, including those whose death may be unknown to the program.

Current Issue

As a result of changes in the availability of SSDMF data, HRSA's Organ Procurement and Transplantation Network (OPTN) and SRTR contractors no longer receive SSDMF information on all OPTN patients directly from SSA. CMS and SSA are negotiating a new arrangement that will allow HRSA contractors to continue receiving these data through CMS. Once this arrangement is in place, some process adjustments with HRSA's contractor will be implemented to ensure that the PSR information is complete. As such, the SRTR PSR reports have been delayed until the data arrangement and processes are in place.

Contingency Plans

Until the release of new SRTR PSR Reports, CMS will continue to use "the most recent SRTR report", as specified in the regulations, which, at this time, is the July 2012 PSRs. The determinations made as a result of surveys conducted using the July 2012 PSRs, remain in force and will continue to be the basis for CMS enforcement action. If a program that was notified of Condition-level outcome non-compliance, based on their July 2012 PSR, opts not to apply for mitigating factors, and a new SRTR report showing compliance, is not released prior to the prospective termination date, the program will face termination from Medicare participation.

Programs are advised that even though they may have more recent unadjusted data that indicates compliance, outside of the mitigating factors process, CMS may not make a compliance determination using that information because it does not follow the regulatory requirements to which we must adhere. More recent unadjusted data may, however, be reviewed through the mitigating factors process outlined under 42 CFR 488.61(c)(4).

Programs that are in Systems Improvement Agreements (SIAs), during the period wherein no new PSRs are being published, can still successfully complete their SIA requirements, if the program's most recent data indicates compliance with CMS Conditions of Participation.

Survey Activities: During the delay in the SRTR PSR release, transplant program routine re-approval and complaint survey activities will continue as usual. The Transplant Program Quarterly Report (TPQR) used on the surveys will contain the July 2012 SRTR PSR information as it is the most recent PSR available.

Effective Date: Immediately. This advisory should be communicated to all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/

Thomas E. Hamilton

cc: Survey and Certification Regional Office Management