Solid Organ Transplant Program Certification Readiness Consulting

Last reviewed October 2026 · https://www.integralhs.com/transplant-program-certification-readiness

What to have ready

Each item below ties to 42 CFR 482 Subpart E or 42 CFR 488.61 (eCFR current as of September 30, 2026) or to SOM Appendix X (Rev. 240, May 1, 2026).

- The hospital's Medicare provider I.D. number (42 CFR 488.61(a), eCFR [https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-488/subpart-B/section-488.61]).
- The names of the designated primary transplant surgeon and primary transplant physician (42 CFR 488.61(a), eCFR [https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-488/subpart-B/section-488.61]).
- "A statement from the OPTN that the center has complied with all data submission requirements" (42 CFR 488.61(a), eCFR [https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-488/subpart-B/section-488.61]).
- A person authorized to sign the request, "for example, a chief executive officer" (42 CFR 488.61(a), eCFR [https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-488/subpart-B/section-488.61]).
- Evidence that the hospital is "a member of and abides by the rules and requirements of the Organ Procurement and Transplantation Network (OPTN)" (42 CFR 482.72, eCFR [https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-482/subpart-E]).
- A transplant volume log: generally 10 transplants over 12 months, or at least 3 for a kidney program, subject to the exceptions in 42 CFR 482.80(d) for heart-lung, pancreas and pediatric requests (42 CFR 482.80(b),(d); 42 CFR 488.61(a)(6)). Also have the program's most recent SRTR one-year patient and graft survival data, which CMS reviews under 42 CFR 482.80(c) and 488.61(a)(2).
- A data submission record showing at least 95 percent of required data submitted to the OPTN within 90 days of the due date (42 CFR 482.80(a), eCFR [https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-482/subpart-E]).
- A written OPO agreement that "identifies specific responsibilities for the hospital and for the OPO with respect to organ recovery and organ allocation" (42 CFR 482.100, eCFR [https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-482/subpart-E]).
- A "written, comprehensive, data-driven QAPI program designed to monitor and evaluate performance of all transplantation services, including services provided under contract or arrangement" (42 CFR 482.96, eCFR [https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-482/subpart-E]).
- Data that are already complete and correct, because under Appendix X the § 482.80 condition is "evaluated by the surveyor off-site, prior to the survey... the program may not submit any additional or corrected data during the survey to change the compliance determination" (SOM Appendix X [https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/som107ap_x_otp.pdf]).