

# Ohio Department of Health Health Care Service Notification Survey

Ohio Department of Health  
Division of Quality Assurance  
Health Care Service Program  
246 North High Street  
Columbus, Ohio 43215  
(614) 466-3325

**Instructions:** The provider of any Health Care Service (HCS) listed under Chapter 3701-84 of the Ohio Administrative Code (OAC) must document compliance with service standards to the Director of Health prior to initiating a new HCS or reactivating a discontinued or temporarily suspended HCS. This form may be used to meet the notification requirements of a new HCS or a reactivated HCS, as set forth in paragraph (B), rule 3701-84-04, OAC.

To document compliance with service standards in Chapter 3701-84 of the OAC, the provider of the HCS must complete section I (general information), section II (service specific information), section III (general compliance checklist), and the Attestation of Compliance form. Compliance with service standards in Chapter 3701-84 of the OAC must be met by the provider of any HCS listed under that Chapter prior to providing the HCS. A variance or waiver may be requested on a separate sheet of paper for any service standard in Chapter 3701-84 not met by the HCS. The granting of a variance or waiver is a discretionary act by the Director of Health based on documentation that the standard is met in an alternative manner for a variance or, for a waiver, that compliance with the standard would cause undue hardship to the HCS and that granting the waiver would not jeopardize the health and safety of any patient.

## Section I: General Information

Provider of the HCS	
Street address	
City	
State	
Postal zip code	
County	
Telephone number	
Hospital registration number	
Mailing address (if different)	
City	
State	
Postal zip code	
Person completing this form	
E-mail address	
Telephone number	
Date	

Check each new HCS which you are seeking to initiate and each HCS you are seeking to reactivate and complete the corresponding service specific information in section II:

HCS	Existing HCS	New HCS	Reactivated HCS
Solid organ transplantation			
Bone marrow transplantation, including stem cell harvesting and reinfusion			
Adult cardiac catheterization			
Adult open heart surgery			
Pediatric cardiac catheterization			
Pediatric cardiovascular surgery			
Pediatric intensive care			

*Unless specified otherwise, a pediatric patient is a patient aged newborn through twenty-one years of age, excluding premature newborns, and an adult patient is a patient twenty-two years of age and older.*

## Section II: Service Specific Information

### Solid Organ Transplantation:

\_\_\_\_\_ Heart

Date HCS will be initiated	
Specify the type of patients served	Adult _____ Pediatric _____
Street address of the HCS	
Building/Floor	
Medical Director	
Telephone number	
E-mail address	
Service contact person	
Telephone number	
E-mail address	
The authorized representative of the provider of the heart transplant service has reviewed the service standards in 3701-84-16 through 3701-84-21, OAC, with the service's medical director and have determined that the service is in full compliance with these requirements.	Yes _____ No _____ If no, identify the standards not met and attach a waiver/variance request or approval
Does the provider have an active adult open heart or pediatric cardiovascular surgery service?	Adult: Yes _____ No _____ Pediatric: Yes _____ No _____
Identify the number of adult open heart and pediatric cardiovascular surgery procedures performed annually*	Adult open heart procedures: _____ Pediatric cardiovascular procedures: _____

\_\_\_\_\_ Lung

Date HCS will be initiated	
Specify the type of patients served	Adult _____ Pediatric _____
Street address of the HCS	
Building/Floor	

Medical Director	
Telephone number	
E-mail address	
Service contact person	
Telephone number	
E-mail address	
The authorized representative of the provider of the lung transplant service has reviewed the service standards in 3701-84-16 through 3701-84-21, OAC, with the service's medical director and have determined that the service is in full compliance with these requirements.	Yes_____ No_____ If no, identify the standards not met and attach a waiver/variance request or approval

\_\_\_\_\_ Liver

Date HCS will be initiated	
Specify the type of patients served	Adult_____ Pediatric_____
Street address of the HCS	
Building/Floor	
Medical Director	
Telephone number	
E-mail address	
Service contact person	
Telephone number	
E-mail address	
The authorized representative of the provider of the liver transplant service has reviewed the service standards in 3701-84-16 through 3701-84-21, OAC, with the service's medical director and have determined that the service is in full compliance with these requirements.	Yes_____ No_____ If no, identify the standards not met and attach a waiver/variance request or approval

\_\_\_\_\_ Kidney

Date HCS will be initiated	
Specify the type of patients served	Adult_____ Pediatric_____
Street address of the HCS	
Building/Floor	
Medical Director	
Telephone number	
E-mail address	
Service contact person	
Telephone number	
E-mail address	
The authorized representative of the provider of the kidney transplant service has reviewed the service standards in 3701-84-16 through 3701-84-21, OAC, with the service's medical director and have determined that the service is in full compliance with these requirements.	Yes_____ No_____ If no, identify the standards not met and attach a waiver/variance request or approval

\_\_\_\_\_ Pancreas

Date HCS will be initiated	
Specify the type of patients served	Adult _____ Pediatric _____
Street address of the HCS	
Building/Floor	
Medical Director	
Telephone number	
E-mail address	
Service contact person	
Telephone number	
E-mail address	
The authorized representative of the provider of the pancreas transplant service has reviewed the service standards in 3701-84-16 through 3701-84-21, OAC, with the service's medical director and have determined that the service is in full compliance with these requirements.	Yes _____ No _____ If no, identify the standards not met and attach a waiver/variance request or approval

\_\_\_\_\_ Small Bowel

Date HCS will be initiated	
Specify the type of patients served	Adult _____ Pediatric _____
Street address of the HCS	
Building/Floor	
Medical Director	
Telephone number	
E-mail address	
Service contact person	
Telephone number	
E-mail address	
The authorized representative of the provider of the small bowel transplant service has reviewed the service standards in 3701-84-16 through 3701-84-21, OAC, with the service's medical director and have determined that the service is in full compliance with these requirements.	Yes _____ No _____ If no, identify the standards not met and attach a waiver/variance request or approval
Does the provider have an active liver transplantation service?	Yes _____ No _____
Identify the number of liver transplant procedures performed annually*	Liver transplants: _____

\_\_\_\_\_ Islet Cell

Date HCS will be initiated	
Specify the type of patients served	Adult _____ Pediatric _____
Street address of the HCS	
Building/Floor	
Medical Director	
Telephone number	
E-mail address	

Service contact person	
Telephone number	
E-mail address	
The authorized representative of the provider of the islet cell transplant service has reviewed the service standards in 3701-84-16 through 3701-84-21, OAC, with the service's medical director and have determined that the service is in full compliance with these requirements.	Yes_____ No_____ If no, identify the standards not met and attach a waiver/variance request or approval

\_\_\_\_\_ **Combination organs**

Specify the organs to be transplanted in combination	
Date HCS will be initiated	
Specify the type of patients served	Adult_____ Pediatric_____
Street address of the HCS	
Building/Floor	
Medical Director	
Telephone number	
E-mail address	
Service contact person	
Telephone number	
E-mail address	
The authorized representative of the provider of the combined organ transplant service has reviewed the service standards in 3701-84-16 through 3701-84-21, OAC, with the service's medical director and have determined that the service is in full compliance with these requirements.	Yes_____ No_____ If no, identify the standards not met and attach a waiver/variance request or approval
Does the provider have an active transplantation service for each organ individually?	Adult: Yes_____ No_____ Pediatric: Yes_____ No_____
Identify the number of individual transplants performed annually for each organ*	Organ _____ Adult transplants: _____ Pediatric transplants: _____ Organ _____ Adult transplants: _____ Pediatric transplants: _____ Organ _____ Adult transplants: _____ Pediatric transplants: _____

\*provide information for the previous 12 months from the time of filing this document

**Bone Marrow Transplantation and Stem Cell Harvesting and Reinfusion:**

\_\_\_\_\_ **Bone Marrow Transplantation**

Date HCS will be initiated	
Specify the type of patients served	Adult_____ Pediatric_____
Specify the type of service	Autologous_____ Allogeneic_____
Street address of the HCS	
Building/Floor	
Medical Director	
Telephone number	

E-mail address	
Service contact person	
Telephone number	
E-mail address	
The authorized representative of the provider of the bone marrow transplant service has reviewed the requirements of 3701-84-24 through 3701-84-27, OAC, with the service's medical director and have determined that the service is in full compliance with these requirements.	Yes_____ No_____ If no, identify the standards not met and attach a waiver/variance request or approval

\_\_\_\_\_ Stem Cell Harvesting and Reinfusion

Date HCS will be initiated	
Specify the type of patients served	Adult_____ Pediatric_____
Specify the type of service	Autologous_____ Allogeneic_____
Street address of the HCS	
Building/Floor	
Medical Director	
Telephone number	
E-mail address	
Service contact person	
Telephone number	
E-mail address	
The authorized representative of the provider of the stem cell harvesting and reinfusion transplant service has reviewed the requirements of 3701-84-24 through 3701-84-27, OAC, with the service's medical director and have determined that the service is in full compliance with these requirements.	Yes_____ No_____ If no, identify the standards not met and attach a waiver/variance request or approval

Adult Cardiac Catheterization:

\_\_\_\_\_ Adult Cardiac Catheterization

Date HCS will be initiated	
Specify the type of service	Level I _____ Level II _____ Level III _____
Street address of the HCS	
Building/Floor	
Medical Director	
Telephone number	
E-mail address	
Service contact person	
Telephone number	
E-mail address	
The authorized representative of the provider of the adult cardiac catheterization service has reviewed	Yes_____ No_____ If no, identify the standards not met and attach a waiver/variance request or approval

the requirements of 3701-84-30 through 3701-84-34.2, OAC, with the service's medical director and have determined that the service is in full compliance with these requirements.	
Is an adult open heart surgery service immediately available and accessible by gurney?	Yes_____ No_____
List specific cardiac catheterization procedures provided	

### Adult Open Heart Surgery

\_\_\_\_\_ Adult Open Heart Surgery

Date HCS will be initiated	
Street address of the HCS	
Building/Floor	
Medical Director	
Telephone number	
E-mail address	
Service contact person	
Telephone number	
E-mail address	
The authorized representative of the provider of the adult open heart surgery service has reviewed the requirements of 3701-84-36 through 3701-84-40, OAC, with the service's medical director and have determined that the service is in full compliance with these requirements.	Yes_____ No_____ If no, identify the standards not met and attach a waiver/variance request or approval

### Pediatric Cardiac Catheterization

\_\_\_\_\_ Pediatric Cardiac Catheterization

Date HCS will be initiated	
Street address of the HCS	
Building/Floor	
Medical Director	
Telephone number	
E-mail address	
Service contact person	
Telephone number	
E-mail address	
The authorized representative of the provider of the pediatric cardiac catheterization service has reviewed the requirements of 3701-84-75	Yes_____ No_____ If no, identify the standards not met and attach a waiver/variance request or approval

through 3701-84-79, OAC, with the service's medical director and have determined that the service is in full compliance with these requirements.	
Is a pediatric cardiovascular surgery service immediately available and accessible by gurney?	Yes_____ No_____

### Pediatric Cardiovascular Surgery

#### \_\_\_\_\_ Pediatric Cardiovascular Surgery

Date HCS will be initiated	
Street address of the HCS	
Building/Floor	
Medical Director	
Telephone number	
E-mail address	
Service contact person	
Telephone number	
E-mail address	
The authorized representative of the provider of the pediatric cardiovascular surgery service has reviewed the requirements of 3701-84-81 through 3701-84-85, OAC, with the service's medical director and have determined that the service is in full compliance with these requirements.	Yes_____ No_____ If no, identify the standards not met and attach a waiver/variance request or approval

### Pediatric Intensive Care

#### \_\_\_\_\_ Pediatric Intensive Care

Date HCS will be initiated	
Street address of the HCS	
Building/Floor	
Medical Director	
Telephone number	
E-mail address	
Service contact person	
Telephone number	
E-mail address	
The authorized representative of the provider of the pediatric intensive care service has reviewed the requirements of 3701-84-61 through 3701-84-65, OAC, with the service's medical director and have determined that the service is in full compliance with these requirements.	Yes_____ No_____ If no, identify the standards not met and attach a waiver/variance request or approval
Is a pediatric cardiac catheterization service immediately available and	Yes_____ No_____

accessible by gurney?	
Is a pediatric cardiovascular surgery service immediately available and accessible by gurney?	Yes_____ No_____

### Section III: General Compliance Checklist

<b>Facility</b>	<b>Yes</b>	<b>No</b>
1. Is the building or structure where the HCS is located in compliance with all applicable federal, state, and local laws and regulations, including but not limited to, building codes?		
2. Is smoking prohibited inside the portion of the structure where the HCS is located?		
3. Is notice posted in a conspicuous place within the area where the HCS is located, stating that smoking is prohibited?		
4. Does the provider of the HCS agree to ensure the director access to the premises, records, and staff to demonstrate compliance with Chapter 3701-84, OAC?		
5. Does the building or structure where the HCS is located have a certificate of use and occupancy?		
6. Is the building or structure where the HCS is located in compliance with state fire code?		
7. Does the provider of the HCS have a disaster preparedness plan that requires conducting practice drills with staff at least once every 6 months?		
8. Are all poisons, hazardous wastes, and flammable materials used in the HCS labeled, stored, and disposed of in a safe manner and in accordance with state and federal laws and regulations?		
9. In determining compliance with space or square footage requirements of chapter 84, OAC, were measurements taken of clear floor space and exclusive of fixed or wall mounted cabinets, desks, and closets that are floor based?		

<b>Patient Care</b>	<b>Yes</b>	<b>No</b>
1. Have comprehensive and effective patient care policies been developed and implemented which ensure the following:		
a. That each patient is treated with consideration, respect, and full recognition of dignity and individuality, including privacy in treatment and personal care needs?		
b. That each patient is allowed to refuse or withdraw consent for treatment or give conditional consent for treatment and that written documentation of patient consent is maintained in the patient's medical record?		
c. That each patient is given access to his or her medical record, unless access is specifically restricted by the attending physician for medical reasons?		
d. That each patient's medical and financial records are kept confidential?		
e. That, if requested, each patient is given a detailed explanation of charges including an itemized bill for services received?		
2. Is each patient of the HCS informed of the following:		
a. The diagnosis and treatment alternatives and risks involved with each?		
b. The provider's policy on advanced directives?		
c. The name of the attending physician or individual supervising the patient's care and the manner in which that individual may be contacted?		
3. Does the provider of the HCS have policies and procedures in place to assure that services are provided in accordance with the patient's plan of care, that all policies and procedures are followed, that applicable current and accepted standards of practice are followed, and that standards set forth in chapter 84, OAC, are met?		
4. Does the provider of the HCS document all medical services performed in the care of the patient in his or her medical record?		
5. Does the provider of the HCS provide for the ancillary and support services necessary for the provision of the service?		
6. Does the provider of the HCS establish and follow written infection control policies and procedures for the surveillance, control and prevention of communicable disease organisms both by contact and airborne routes that is consistent with current infection control guidelines issued by the CDC?		
7. Does the provider of the HCS facilitate the activities associated with the prevention and spread of communicable infectious diseases?		

8. Does the provider of the HCS have written policies and procedures that address the following:		
a. Utilization of protective clothing and equipment?		
b. Storage,, maintenance, and distribution of sterile supplies and equipment?		
c. Disposal of biological waste; including blood, body tissue, and fluid, in accordance with Ohio law?		
d. Universal precautions body substance isolation or equivalent?		
e. Tuberculosis and other airborne diseases?		
9. Does the provider of the HCS have written policies and procedures to assure the proper maintenance of equipment and safe operation in accordance with the manufacturer's instructions?		
10. Is each patient of the HCS or the patient's representative provided the following:		
a. Instruction and education regarding the services to be performed?		
b. Written information about how to obtain appointments and needed services both during and after the HCS's normal hours of operation?		
c. Verbal and written instructions for post-treatment care and procedures for obtaining emergency care?		

<b>Personnel and Staffing</b>	<b>Yes</b>	<b>No</b>
1. Does the provider of the HCS maintain a sufficient number of qualified staff and other personnel and an appropriate schedule of staff time to meet the needs of the patients in a timely manner?		
2. Does the provider of the HCS utilize only appropriately trained and qualified personnel?		
3. Does the provider of the HCS assure that those staff members who function in a professional capacity meet the standards applicable to that profession, including possessing a current Ohio license, registration, or certification, as required by law, and are working within their scope of practice?		
4. Does the provider of the HCS maintain copies of current Ohio licenses, registrations and certifications in the employee's personnel files or does the provider have an established system to verify and document the possession of such?		
5. Does each HCS have an appropriately credentialed medical director?		
6. Does the provider of the HCS document and follow a tuberculosis control plan that is based on the provider's assessment of the HCS that is consistent with the CDC "Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health Care Settings, 2005"?		
7. Does the provider of the HCS have measures in place to prevent a staff member from providing services if the staff member has a disease capable of being transmitted during the performance of his or her duties, is under the influence of drugs or alcohol, or has not demonstrated sufficient knowledge or expertise for the position?		
8. Does the provider of the HCS provide all staff with appropriate orientation and training regarding the HCS's equipment, safety guidelines, practices, and policies?		
9. Does the provider of the HCS perform evaluations of each staff member no less than every 36 months?		
10. Is there an on-going process for ensuring the competence of staff which includes a periodic assessment and re-determination of necessary skill levels and determination of whether each staff member has achieved the skill levels?		
11. Does the provider of the HCS retain staffing schedules, time-worked schedules, on-call schedules, and payroll records for at least 2 years?		

<b>Medical Records</b>	<b>Yes</b>	<b>No</b>
1. Does the provider of the HCS maintain confidential medical records for each patient that clearly document the patient's needs, assessments, and services rendered?		
2. Are patient records maintained for 5 years after discharge?		

<b>Quality Assessment and Improvement</b>	<b>Yes</b>	<b>No</b>
1. Does the provider of the HCS have a written quality assessment and improvement plan for each HCS that describes the plan's objectives, organization, scope, and mechanism for overseeing the effectiveness of monitoring, evaluation, improvement, and problem-solving activities?		
2. Does the quality assessment and improvement program do all of the following:		
a. Monitor and evaluate all aspects of care, including effectiveness, appropriateness, accessibility, continuity, efficiency, patient outcome, and patient satisfaction?		
b. Establish expectations, develop plans, and implement procedures to assess and improve the quality of care and resolve identified problems?		
c. Establish expectations, develop plans, and implement procedures to assess and improve the HCS's governance, management, clinical and support processes?		
d. Establish information systems and appropriate data management processes to facilitate the collection, management, and analysis of data needed for quality improvement?		
e. Internally document and report findings, conclusions, actions taken, and the results of any actions taken to the HCS's management and medical director?		
f. Document and review all unexpected complications and adverse events, being serious injury or death resulting from medical management, which arise during the provision of the service or during the hospital stay?		
g. Hold regular meetings, chaired by the medical director of the HCS, or designee, and meet at least within 60 days after a death or complication to review all deaths and complications and to report findings?		
h. Investigate and remedy any patterns that might indicate a problem?		

<b>Complaints</b>	<b>Yes</b>	<b>No</b>
1. Does the provider of the HCS have policies and procedures to receive, investigate, report findings, and take action on complaints regarding the quality and appropriateness of services?		
2. Is the toll free complaint hotline of the Ohio Department of Health's complaint unit posted in a conspicuous place in the area where the HCS is provided?		

## Ohio Department of Health Health Care Services Attestation of Compliance

An Attestation of Compliance must be signed by the authorized representative of the provider of the Health Care Service (HCS) and the Medical Director for each service. A separate Attestation of Compliance form must be completed for each HCS and for each Medical Director.

Based on personal knowledge and belief, I attest that the \_\_\_\_\_ service for which the undersigned is the medical director, at \_\_\_\_\_, the provider of the HCS, in \_\_\_\_\_, Ohio currently meets and will continue to meet the applicable statutory and regulatory requirements in section 3702.11 through 3702.20 of the Ohio Revised Code and Chapter 3701-84 of the Ohio Administrative Code.

I understand that falsifying or materially misrepresenting any information in this Attestation of Compliance will result in enforcement action. I understand that timely notification to the Director of Health is required upon any material change in the HCS offered or any change in the undersigned personnel on this attestation. I further understand that the Ohio Department of Health has the right to conduct an inspection at any time to validate whether the statements made in this Attestation of Compliance are true.

Specify the service for which the undersigned is the Medical Director		
Signature of the Medical Director of the HCS		Date
Typed Name	Telephone	E-mail address
Signature of authorized representative of the provider of the HCS		Date
Typed Name	Telephone	E-mail address
Title/relationship to the provider of the HCS		

Please return to: Ohio Department of Health  
Division of Quality Assurance  
Health Care Services Section  
246 North High St.  
Columbus, Ohio 43215

Contact Information: Telephone: 614-466-3325  
Fax: 614-564-2480  
E-mail: [HCSDATA@odh.ohio.gov](mailto:HCSDATA@odh.ohio.gov)