

Adult Heart and HeartLung Status 2 Initial Justification Form M
Fields to be completed by members

Form Section	Field Label
Status 2 Justification Form Section IV	Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device (LVAD)
Status 2 Justification Form Section IV	Total artificial heart (TAH), BiVAD, right ventricular assist device (RVAD), or ventricular assist device (VAD) for single ventricle patients
Status 2 Justification Form Section IV	Mechanical circulatory support device (MCSD) with malfunction
Status 2 Justification Form Section IV	Percutaneous endovascular mechanical circulatory support device
Status 2 Justification Form Section IV	Within 7 days prior to support (select one of the following)
Status 2 Justification Form Section IV	Cardiac index
Status 2 Justification Form Section IV	Cardiac index - Test Date
Status 2 Justification Form Section IV	Cardiac index - Test Time
Status 2 Justification Form Section IV	Pulmonary capillary wedge pressure
Status 2 Justification Form Section IV	Pulmonary capillary wedge pressure - Test Date
Status 2 Justification Form Section IV	Pulmonary capillary wedge pressure - Test Time
Status 2 Justification Form Section IV	Systolic blood pressure
Status 2 Justification Form Section IV	Systolic blood pressure - Test Date
Status 2 Justification Form Section IV	Systolic blood pressure - Test Time
Status 2 Justification Form Section IV	And the candidate (select one of the following)
Status 2 Justification Form Section IV	A continuous infusion of at least one high dose intravenous inotrope
Status 2 Justification Form Section IV	A continuous infusion of at least two intravenous inotropes

Status 2 Justification Form Section IV	Date of administration of CPR
Status 2 Justification Form Section IV	Date of administration of CPR - Test Time
Status 2 Justification Form Section IV	Systolic blood pressure
Status 2 Justification Form Section IV	Systolic blood pressure - Test Date
Status 2 Justification Form Section IV	Systolic blood pressure - Test Time
Status 2 Justification Form Section IV	Arterial lactate
Status 2 Justification Form Section IV	Arterial lactate - Test Date
Status 2 Justification Form Section IV	Arterial lactate - Test Time
Status 2 Justification Form Section IV	Aspartate transaminase
Status 2 Justification Form Section IV	Aspartate transaminase - Test Date
Status 2 Justification Form Section IV	Aspartate transaminase - Test Time
Status 2 Justification Form Section IV	Alanine transaminase
Status 2 Justification Form Section IV	Alanine transaminase - Test Date
Status 2 Justification Form Section IV	Alanine transaminase - Test Time
Status 2 Justification Form Section IV	Intra-aortic balloon pump (IABP)
Status 2 Justification Form Section IV	Within 7 days prior to support (select one of the following)
Status 2 Justification Form Section IV	Cardiac index
Status 2 Justification Form Section IV	Cardiac index - Test Date
Status 2 Justification Form Section IV	Cardiac index - Test Time
Status 2 Justification Form Section IV	Pulmonary capillary wedge pressure
Status 2 Justification Form Section IV	Pulmonary capillary wedge pressure - Test Date

Status 2 Justification Form Section IV	Pulmonary capillary wedge pressure - Test Time
Status 2 Justification Form Section IV	Systolic blood pressure
Status 2 Justification Form Section IV	Systolic blood pressure - Test Date
Status 2 Justification Form Section IV	Systolic blood pressure - Test Time
Status 2 Justification Form Section IV	And the candidate (select one of the following)
Status 2 Justification Form Section IV	A continuous infusion of at least one high dose intravenous inotrope
Status 2 Justification Form Section IV	A continuous infusion of at least two intravenous inotropes
Status 2 Justification Form Section IV	Date of administration of CPR
Status 2 Justification Form Section IV	Date of administration of CPR - Test Time
Status 2 Justification Form Section IV	Systolic blood pressure
Status 2 Justification Form Section IV	Systolic blood pressure - Test Date
Status 2 Justification Form Section IV	Systolic blood pressure - Test Time
Status 2 Justification Form Section IV	Arterial lactate
Status 2 Justification Form Section IV	Arterial lactate - Test Date
Status 2 Justification Form Section IV	Arterial lactate - Test Time
Status 2 Justification Form Section IV	Aspartate transaminase
Status 2 Justification Form Section IV	Aspartate transaminase - Test Date
Status 2 Justification Form Section IV	Aspartate transaminase - Test Time
Status 2 Justification Form Section IV	Alanine transaminase
Status 2 Justification Form Section IV	Alanine transaminase - Test Date
Status 2 Justification Form Section IV	Alanine transaminase - Test Time

Status 2 Justification Form Section IV	Ventricular tachycardia (VT) or ventricular fibrillation (VF)
Status 2 Justification Form Section IV	Exception for status 2
Status 2 Justification Form Section IV	This exception request is specifically related to a device recall
Status 2 Justification Form Section IV	Clinical Narrative

OMB No. 0915-0157; Expiration Date: XX/XX/20XX

PUBLIC BURDEN STATEMENT:

The private, non-profit Organ Procurement and Transplantation Network (OPTN) collects this information functions: to assess whether applicants meet OPTN Bylaw requirements for membership in the OPTN organizations with OPTN Obligations. An agency may not conduct or sponsor, and a person is not required to respond to, unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0915-0157. This information collection is required to obtain or retain a benefit per 42 CFR §121.11(b) Act protection (Privacy Act System of Records #09-15-0055). Data collected by the private non-profit Contractor's security features. The Contractor's security system meets or exceeds the requirements a Security of Federal Automated Information Systems, and the Department's Automated Information System reporting burden for this collection of information is estimated to average 0.27 hours per response, including searching existing data sources, gathering the data, reviewing the collection of information, and completing and reviewing the collection of information. Send comments or other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Fishers Lane, Room 14N39, Rockville, Maryland, 20857 or paperwork@hrsa.gov.

Medical Urgency Data

Notes

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tion in order to perform the following OPTN
; and to monitor compliance of member
quired to respond to, a collection of information
a collection is 0915-0157 and it is valid until
) (2). All data collected will be subject to Privacy
OPTN also are well protected by a number of the
is prescribed by OMB Circular A-130, Appendix III,
ystems Security Program Handbook. The public
including the time for reviewing instructions,
nments regarding this burden estimate or any
Information Collection Clearance Officer, 5600