

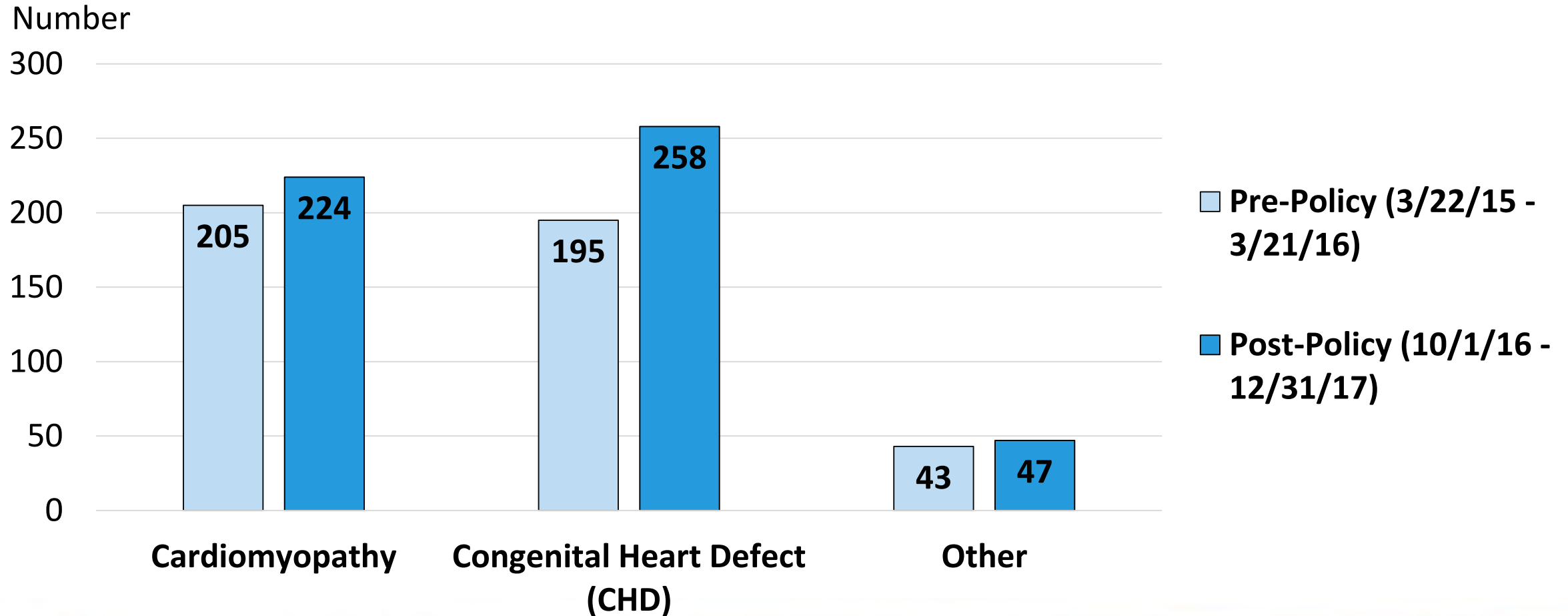
Guidance Addressing the Use of Pediatric Heart Exceptions

OPTN Heart Transplantation Committee

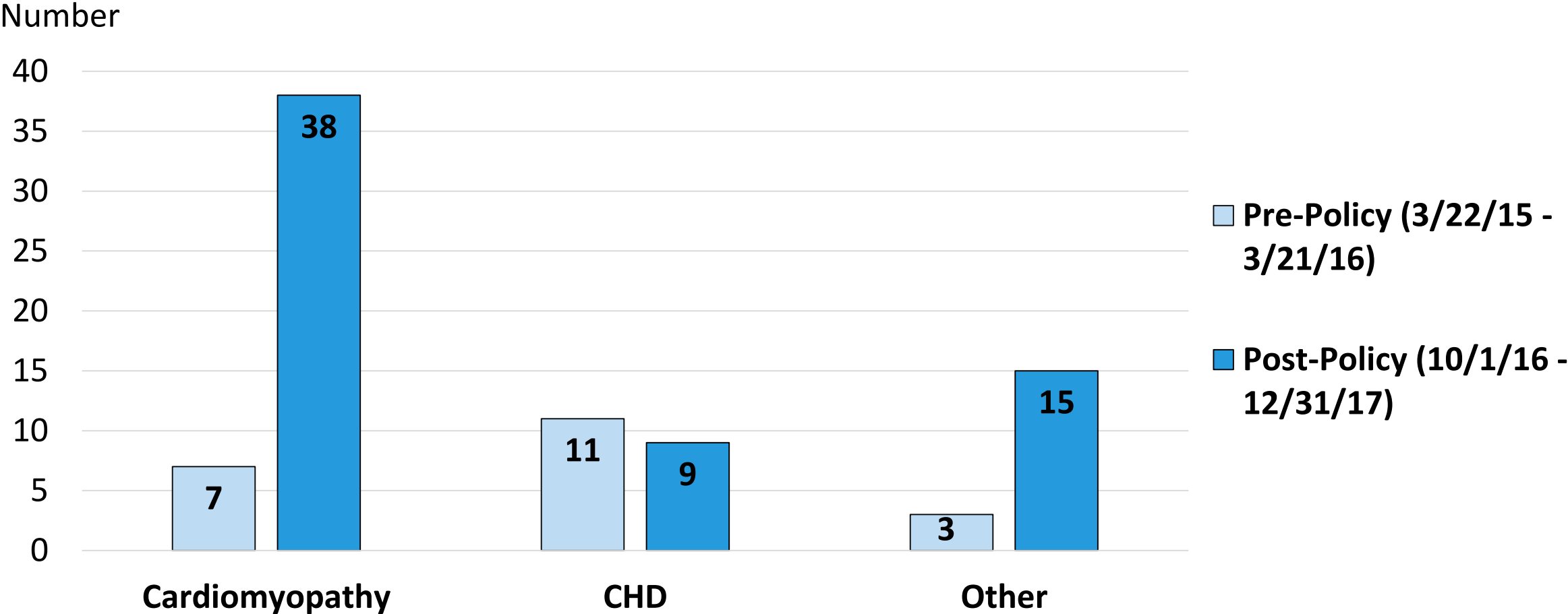
Purpose of Guidance Document

- Increase equal access to transplant for medically urgent, unique pediatric candidates
- Provide consistent guidance for review of following diagnoses:
 - Dilated cardiomyopathy
 - Hypertrophic or restrictive cardiomyopathy
 - Single ventricle heart disease
 - Coronary allograft vasculopathy and retransplantation
- Assist in activities of the National Heart Review Board for pediatric candidates
- Increase efficiency of review process by providing guidance on specific information to include in an exception request

Pediatric Heart Transplants at All Statuses by Diagnosis



Pediatric Heart Transplants at Status 1A by Exception and Diagnosis



Dilated Cardiomyopathy Guidance

- Pediatric candidates may be eligible for Status 1A exception if:
 - Under 5 kg and:
 - Admitted to hospital of listing
 - Supported by a continuous infusion of at least one high-dose intravenous inotrope OR a continuous infusion of at least two intravenous inotropes
 - Under 10 kg and:
 - Meets conditions above AND has evidence of poor systemic perfusion
 - Over 10 kg:
 - Presence of contraindications to mechanical circulatory support

Restrictive or Hypertrophic Cardiomyopathy Guidance

- Pediatric candidates may be eligible for Status 1A exception if
 - Admitted to hospital of listing and meets **any** of the following criteria:
 - Supported by a continuous infusion of at least one high-dose intravenous inotrope **OR** a continuous infusion of at least two intravenous inotropes
 - Has had an episode of sudden death or recurrent prolonged runs of hemodynamically significant arrhythmia that are not controlled by medical therapy
 - Has had syncopal episodes felt to be related to restricted ventricular filling
 - Has evidence of increased pulmonary vascular resistance (exceeding 6 WU*m²)

Single Ventricle Heart Disease Guidance

- Pediatric candidates with this CHD may be eligible for Status 1A exception if:
 - Admitted to hospital of listing **AND**
 - Experiencing complications related to their congenital heart disease **AND**
 - Is actively receiving therapy for said complication, without regard for change in the candidate's cardiac support
- Pediatric candidates may be eligible for Status 1B exception if palliated through a Fontan procedure

Coronary Allograft Vasculopathy (CAV) and Retransplantation Guidance

- Pediatric candidate may be eligible for Status 1A exception if:
 - Prior heart transplant and evidence of chronic rejection or significant CAV **AND**
 - History of recent cardiac arrest, or signs or symptoms placing patients at high-risk for sudden cardiac death
- Pediatric candidates may be eligible for Status 1B exception if
 - Has a history of revascularization (either surgical or transcatheter) for CAV

Standard Information for Pediatric Heart Exception Requests

- Requests specific description of candidate's current diagnoses and methods of support, inclusive of inotropes and mechanical circulatory support
- Specifically describe how:
 - The candidate meets the exception criteria, or
 - Why standard therapies may not be ideal
- Describe why the current policy does not adequately account for the candidate's particular situation and high risk of waitlist mortality

Feedback Requested

- Are there other contraindications to the use of a Ventricular Assist Device (VAD) that should be considered?
- What, if any, measure of sensitization could be included to assist in determining whether a Coronary Allograft Vasculopathy candidate should be considered for Status 1A listing by exception?
- What other considerations would make this guidance more useful?

Please introduce yourself when you speak

Guidance Addressing the Use of Pediatric Heart Exceptions

- Guidance is provided to determine status exception requests for candidates with the diagnoses of:
 - Dilated cardiomyopathy
 - Hypertrophic or restrictive cardiomyopathy
 - Single ventricle heart disease
 - Coronary allograft vasculopathy and retransplantation
- Outlines standard information to include when submitting pediatric heart exception requests

Feedback is summarized and shared as public comment