

ROCKVILLE POLICY
DEVELOPMENT
DISCUSSION

APRIL 9, 2010

ROCKVILLE POLICY DEVELOPMENT DISCUSSION

ATTENDANCE

Chris McLaughlin (HRSA), Emily Levine (HRSA), Joyce Somsak (HRSA), Rich Durbin (HRSA), Jim Bowman (HRSA), Bernie Koslovsky (HRSA), Patricia Stroup (HRSA), Walter Graham (UNOS/OPTN), James Wynn (UNOS/OPTN), Charlie Alexander (UNOS/OPTN), Mary D. Ellison (UNOS/OPTN), Connie Davis (UNOS/OPTN), Maryl Johnson (AST), Joren Madsen (AST), Susan Nelson (AST), Katrina Crist (ASTS), Bob Merion (ASTS), Catherine Garvey (NATCO), Janene Dawson (NATCO)

SUMMARY

Representatives of the ASTS, the AST, NATCO, OPTN/UNOS, and HRSA met on April 9, 2010 to discuss and develop a new process for incorporating clinical input into developing OPTN/UNOS policies with the potential to direct or prescribe medical care. The need for such a process has been identified during the course of OPTN/UNOS's attempts to develop policies that are more specific and detailed regarding OPTN/UNOS member requirements in the area of living donor protections.

During the discussion, it was noted that early involvement of the societies in the OPTN/UNOS policy development process, for the purpose of identifying the appropriate medical requirements and the appropriate level of specificity of such requirements, would be an important advance. Hopefully, this will allow policies to be developed in a timelier manner and will foster their acceptance by the transplant community at large.

A general process was agreed upon, which will be piloted during OPTN/UNOS's continuing efforts to expand its current requirements in the area of living donor medical evaluation (including psychosocial evaluation), informed consent, and post-donation follow-up.

PROCESS

The general process will proceed as follows:

- I. Quarterly, the **Joint Society Policy Steering Group** will meet via conference call to review the current and planned policy agenda of OPTN/UNOS. OPTN/UNOS will host each call, using Microsoft Live Meeting. Specific policy development activities will be described so that each clinical society can determine, over a 2-week period after the call, whether any policy under development has the potential to prescribe medical care.

The Joint Society Policy Steering Group will comprise representatives of the AST, ASTS and NATCO as well as the OPTN/UNOS President or his/her designee. Each society will identify its standing representative on an annual basis. The quarterly calls may be attended by the society and UNOS executive directors, as well as HRSA staff. Each member society may be represented by a substitute upon the agreement of its president or executive director.

UNOS support staff will also attend in order to set up the calls, facilitate the presentations, and document the proceedings. Approximately 2 weeks after each quarterly call, the Steering Group will reconvene in order to identify policies in development that have the potential to prescribe medical care. A vote of the non-OPTN/UNOS Steering Group members will be taken on each such policy under consideration. A majority approval vote of the three society representatives will be required to invoke the rest of the process.

In the event that 2 of the 3 clinical societies conclude that the special process does NOT need to be invoked for a particular policy issue, the dissenting society will pursue its own approach to ensuring input into the OPTN/UNOS policy process, through existing mechanisms in the OPTN/UNOS policy development process (e.g., attending OPTN/UNOS meetings, providing input through committee members, participating in OPTN/UNOS public comment, etc.).

- II. For any policy voted by the non-OPTN/UNOS members of the Steering Group to direct or prescribe medical care, a **Joint Society Policy Working Group** will be formed. The Working Group's charge (scope and goals for what is to be accomplished) will be defined by the Steering Group. The length of time each Working Group will have to complete its work will be determined by the Steering Committee with input from OPTN/UNOS and HRSA. Each Working Group will consist of up to 3 member representatives selected by each organization (AST, ASTS, NATCO, and OPTN/UNOS). The OPTN/UNOS representatives will be members of the OPTN/UNOS committee that is sponsoring the policy in question, and will regularly apprise the sponsoring OPTN/UNOS committee of the Working Group's progress. Although each organization will typically have an equal number of representatives, this may vary by mutual agreement of the organizations, and the Steering Group may ask representatives of other organizations to participate as needed. HRSA representatives may also attend conference calls and meetings of the Working Group. A UNOS staff member will arrange calls and meetings of the Working Group as requested and will provide reports of each meeting, to be approved by the Working Group chair.
 - a. The first item of business for each Working Group will be the election of a chair from among its non-OPTN/UNOS members. The non-OPTN/UNOS representatives participate in the vote. The Working Group will next consider whether persons with special expertise should be added to the group and will suggest either individuals or organizations that should be added or consulted, with input from the Steering Group and DoT/HRSA as appropriate. UNOS staff will assist the Working Group in contacting

additional individuals or organizations and arranging their participation in the Working Group.

- b. The Working Group will provide its perspectives on the scope and goals of the policy in development, as well as specific recommendations for policy content.
- c. The Working Group will also assure OPTN/UNOS that the input provided represents the opinions and views of the societies.
- d. Recommendations developed by the Working Group will include the following:
 - level of specificity to be required in the OPTN/UNOS policy;
 - specific policy provisions, differentiating between what would be required and what would be optional or recommended;
 - the evidence basis for each recommendation (which may consist not only of data and published literature, but also opinion on generally accepted medical practice);
 - the period of time within which requirements should be revisited for currency;
 - any pertinent comments on cost implications for members, patients, OPTN/UNOS.

The Working Group will also identify key policy components that it would recommend be used by OPTN/UNOS in assessing policy compliance by the members, and will consider how it envisions OPTN/UNOS would monitor member compliance, using information provided by UNOS staff about mechanisms available to OPTN/UNOS for this purpose.

Should disagreements regarding policy content arise, they will be decided by majority vote of the non-OPTN/UNOS members of the working group.

- III. Once the Working Group's final recommendations are available, the Group's input will be provided to the Steering Committee for review and endorsement.
 - a. After Steering Committee approval, the recommendations will be provided to the OPTN/UNOS Committee sponsoring the developing policy for incorporation into the OPTN/UNOS policy development process.
 - b. The recommendations will be presented to the OPTN/UNOS committee by the Working Group chair.
 - c. The Working Group Chair will then participate in subsequent meetings of the sponsoring OPTN/UNOS committee as it continues the policy development process (e.g., policy formulation, public comment, and Board review).

- d. The Working Group chair will not be a member of the OPTN/UNOS committee and will not have a vote.
- e. In the event that the OPTN/UNOS committee disagrees with a substantial number of the Working Group's recommendations, discussion between the 2 groups will occur in an attempt to arrive at consensus.

OPTN/UNOS committee reports, public comment documents, and Board reports describing policies developed with the aid of this new process will include a description of the whole process and the deliberations and considerations involved.

PILOTING THE PROCESS

To pilot this process during the further development of OPTN/UNOS living donor requirements, a Working Group will be formed immediately following the review and approval of this summary and as soon as UNOS can identify staff to support the new process. The Working Group will provide recommendations to OPTN/UNOS regarding appropriate requirements for the medical evaluation (including psycho-social evaluation) and informed consent of potential living kidney donors as well as post-donation follow-up and data submission. The Group must provide final recommendations to OPTN/UNOS within 12 months of its formation, or approximately June 2011. The OPTN/UNOS Living Donor Committee will then finalize a policy proposal, issue it for public comment, and continue any policy development and consensus building necessary for continued policy review and approval.