Comments on Proposed Ways and Means/Senate Finance Committee Draft Outline on Physician Payment Reform

The American Society of Transplant Surgeons (ASTS) is pleased to have the opportunity to comment on the Ways and Means/Senate Finance Committee Joint Proposal on Physician Payment Reform (the "Joint Proposal"). The ASTS is a medical professional society comprised of over 2000 transplant surgeons, physicians, scientists, advanced transplant providers and allied health professionals dedicated to excellence in transplant surgery through education and research with respect to all aspects of organ donation and transplantation.

ASTS very much appreciates the efforts made by Congressional leaders and their staffs to address the problems raised by the application of the Sustainable Growth Rate (SGR) to Medicare Physician Fee Schedule allowances. In general, while we believe that the Joint Proposal most certainly could be clarified and potentially improved in some areas, it is imperative for the physician community and Congress to reach an accommodation on the SGR repeal in order to address the challenges of improving the quality and lowering the cost of health care for all of our patients. For this reason, we support the efforts of the Committees.

The Joint Proposal is complex and multi-faceted, and it is impossible for us to conduct a full review of the potential implications of the proposal on our members in time to meet the Committees' necessarily tight timeframe. For this reason, our comments focus on those provisions of the Joint Proposal that are of particular interest to our members.

Quality Component of the Value Based Purchasing Program included in the Joint Proposal. (Joint Proposal Section II; Value-Based Purchasing Program, Assessment Categories, Quality measures).

The Joint Proposal includes provisions that would allocate funds to professional societies and others for the development of additional quality measures. ASTS strongly supports this initiative, and believes that additional measure development has the potential to ensure that the entire medical community becomes more actively engaged in quality improvement

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However, we are concerned that, in the section of the Joint Proposal related to the new quality component of the Value-Based Purchasing Program, the Joint Proposal states:

> **Quality measures** used in the current law PQRS and other incentive programs would be used for the quality category.

While the Joint Proposal further states that "additional weight" is to be given to outcomes measures, the Joint Proposal fails to recognize that the current PQRS measures and quality measures in the context of other programs are virtually invariably process measures. While we recognize that many entities have invested considerable sums in the current quality reporting measures and systems, we urge the Committees to draft the new quality program in a manner that precludes the Centers for Medicare and Medicaid Services (CMS) from recreating the bureaucracy inherent in the current PQRS system.

We are particularly concerned that, even though Congress authorized the approval of Qualified Clinical Data Registries (QCDRs) to provide professional medical associations and others flexibility in defining (and implementing systems for measuring) clinically relevant measures, the CMS has proposed an administratively burdensome, regulatory approach to implementing the QCDR statutory provisions. CMS appears to want to remake QCDRs in the image of PQRS, rather than allowing QCDRs to serve as a true alternative to the PQRS' more bureaucratic and process oriented approach.

ASTS respectfully submits that transplantation should serve as a model for quality measure reporting for other specialties and, in particular, for surgical specialties. Transplant surgeons participate in the Scientific Registry of Transplant Recipients (SRTR)[1], a comprehensive national database of transplantation statistics. The SRTR transplant program reports include:

- Reliable transplant information for patients, families and medical professionals;
- A complete list of U.S. transplant centers;
- Waiting time and organ availability data; and
- Survival statistics for waitlisted and for transplanted patients.

The SRTR provides detailed patient and organ survival and other outcome information for every transplant for each transplant center and each type of organ transplant (i.e., kidney, liver, heart,

[1] The SRTR operates under contract with the Health Resources and Services Administration (HRSA), a sister agency to CMS within HHS. Participation in the SRTR is mandatory. The SRTR is an electronic, secure registry. SRTR reporting is audited by the Organ Procurement and Transplantation Network (OPTN), which operates under a separate HRSA contract.

heart-lung, pancreas, intestine, kidney-pancreas). This is precisely the type of specific, accessible outcome information that patients and prospective patients want and need. Each center's performance is risk adjusted and reported against applicable benchmarks: Actual performance is compared to "expected" performance on key measures, taking into account sophisticated (albeit as-yet-imperfect) risk adjustment methodologies. We invite you to explore the SRTR website at greater length at www.srtr.org/local_stats.aspx.

Thus, in the field of transplantation, there is a registry (the SRTR) that:

- Gathers data on clinical outcomes (not process), and presents this data in a manner that is easily understood by patients, clinicians, regulatory authorities and the general public;
- Is based on the concept of team-based reporting, thus facilitating cooperation and coordination of care;
- Is operated by an independent entity under contract with the federal government and is therefore free of potential bias or manipulation by providers;
- Incorporates reasonable (albeit not perfect) risk adjustment methodologies that facilitate comparison of the performance of transplant centers throughout the country.

Yet, under CMS' proposed QCDR regulations the SRTR (as currently operated) likely would not be approved as a QCDR, since the SRTR reports outcomes, rather than the multiplicity of PQRS process measures required in CMS' QCDR proposed regulations; and since it gathers data on a team-based approach rather than on the basis of a single surgeon..

We note that the Joint Proposal includes a provision that may address some of these problems. The Joint Proposal states:

> Professionals can opt to assess their quality performance (and other categories as the Secretary deems appropriate) at the group level, including the election of virtual groups for professionals in practices of ten or fewer. In addition, starting in 2014, group-level quality-reporting credit would be available for groups reporting to a qualified clinical data registry. The Secretary could also allow hospital or other facility-based professionals to have their quality assessment determined by the performance of their affiliated hospital or facility

We strongly support these changes. In addition, we urge the Committees to draft the quality related provisions of the final SGR legislation in a manner that facilitates the development and

recognition of team based outcomes registries, like SRTR, as QCDRs. Model legislative language is attached (**Appendix A**).

Expanding the Use of Medicare Data for Performance Improvement. .

The Joint Proposal includes a requirement (in the section entitled, "VII. Expanding the Use of Medicare Data for Performance Improvement,") that would require the Secretary to make Medicare data available to QCDRs to support quality improvement activities. Unfortunately, due to fraud issues that are entirely unrelated to registry activity, in November 2011, the Social Security Administration (SSA) restricted access to certain death record data in the Social Security Administration's publicly available Death Master File (DMF), dropping the death data available to the SRTR by about 33%. Due to the impact of incomplete death ascertainment on the accuracy of the reports issued by the SRTR on individual transplant programs, HRSA instructed SRTR to halt production of publicly available reports on individual transplant centers until other data sources reporting patient status information could be identified. As a result, the following notice is now prominently displayed on the SRTR website while a solution is developed (http://www.srtr.org/csr/current/Centers/Default.aspx):

> **The transplant program reports currently posted on this website were released in July 2012. Updated reports are not available.**

Currently SSA shares a full version of the DMF with CMS, which utilizes the file to preclude payment of federal benefits to deceased beneficiaries. ASTS respectfully requests that the language related to access to Medicare data referenced in Section VII of the Joint Proposal be drafted in a manner that specifically allows QCDRs access to the Social Security Death Master File and other non-claims data (e.g. data related to disability) necessary for clinical data registries to report on the health outcomes of clinical interventions. Provisions can and should be included in the governing legislation requiring QCRDs to utilize such data solely for the purpose of determining the outcomes of clinical interventions and to keep individually identifiable data confidential. Model legislative language is included for the Committees' consideration (**Appendix B**).

We appreciate the opportunity to comment on the Joint Proposal. If you have any questions related to the ASTS position on the Joint Proposal or related matters, please do not hesitate to contact: Kim Gifford, ASTS Executive Director, at kim.gifford@asts.org or ASTS Washington counsel, Peggy Tighe (Peggy.Tighe@ppsv.com) or Diane Millman (Dmillman@ppsv.com).

Appendix A

Proposed Language to Facilitate Flexibility in the Approval of Qualified Clinical Data Registries.

``(E) Qualified clinical data registry.--

``(i) In general.--The Secretary shall establish requirements for an entity to be considered a qualified clinical data registry. Such requirements shall include a requirement that the entity provide the Secretary with such information, at such times, and in such manner, as the Secretary determines necessary to ~~carry out this Subsection~~ *ensure that the qualified clinical data registry meets the criteria set forth in subparagraph (ii) hereof*.

``(ii) Considerations.--In establishing the requirements under clause (i), the Secretary shall ~~consider~~ *limit consideration of whether an entity qualifies as a qualified clinical data registry to* whether an entity--

``(I) has in place mechanisms for the transparency of data elements and specifications, risk models, and measures;

``(II) requires the submission of data from participants with respect to multiple payers;

``(III) provides timely performance reports to participants at the individual participant *or group level (provided, however, that, any participant who hospital or facility based shall have the option to have assessment based on the performance of the affiliated hospital or facility)*; and

``(IV) supports quality improvement initiatives for participants.

``(iii) Measures.--With respect to measures used by a qualified clinical data registry--

``(I) sections 1890(b)(7) and 1890A(a) shall not apply; and

``(II) measures endorsed by the entity with a contract with the Secretary under section 1890(a) may be used*; and*

(III) measures of health care outcomes may be used regardless of whether such measures are endorsed by an entity with a contract with the Secretary under section 1890(a).

Notwithstanding any of the requirements otherwise applicable to a qualified clinical data registry, the Secretary shall recognize as a qualified clinical data registry any registry that operates under contract with the Secretary and that collects outcomes data

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on procedures specified in such contract (such as the Scientific Registry of Transplant Recipients (SRTR).

``(iv) Consultation.--In carrying out this subparagraph, the Secretary shall consult with interested parties.

``(v) Determination.--The Secretary shall establish a process to determine whether or not an entity meets the requirements established under clause (i). Such process may involve one or both of the following:

``(I) A determination by the Secretary.

``(II) A designation by the Secretary of one or more independent organizations to make such determination.''

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Appendix B

Proposed Legislative Language to Facilitate Release of SSDMF Data to QCDRs

.—Consistent with applicable laws and regulations with respect to privacy and other rel-
1evant matters, *and notwithstanding Section 205(r) of the Social Security Act*,
the Secretary shall provide such Medicare claims data, *death records data, and other data collected or retained by the Secretary* as may be necessary for a qualified clinical data registry under section 1848(m)(3)(E)) of the Social Security Act (42 11 U.S.C. 1395w–4(m)(3)(E)) for purposes of linking such data with clinical outcomes data and performing analysis and research to support quality improvement activities.