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PHYSICIAN CLINICAL REGISTRY COALITION

June 27, 2016

Mr. Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5517-P, P.O. Box 8013
Baltimore, MD 21244-8013

[Submitted online at: https://www.regulations.gov/#!docketDetail;D=CMS-2016-0060]

Re: CMS-5517-P – Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models

Dear Mr. Slavitt:

The undersigned members of the Physician Clinical Registry Coalition (the Coalition) appreciate the opportunity to comment on the proposed rule on the implementation of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114-10) provisions related to MIPS and APMs (the Proposed Rule).[1] The Coalition is a group of more than 20 medical societies and other physician-led organizations that sponsor clinical data registries that collect and analyze clinical outcomes data to identify best practices and improve patient care. We are committed to advocating for policies that enable the development of clinical data registries and enhance their ability to improve quality of care through the analysis and reporting of these outcomes. Over half the members of the Coalition have been approved as qualified clinical data registries (QCDRs) and most of the other members are working towards achieving QCDR status.

MACRA requires the Secretary of the Department of Health and Human Services (HHS) to encourage the use of QCDRs and certified EHR technology (CEHRT) for reporting measures under the Quality performance category.[2] The Coalition commends the Centers for Medicare & Medicaid Services (CMS) for implementing the MACRA requirements and encouraging the use of QCDRs for reporting MIPS data under MACRA. Specifically, the Coalition is pleased that the Proposed Rule at 42 C.F.R. § 414.1400(a)(2) expands the capability of QCDRs to submit data for the Clinical Practice Improvement Activity (CPIA), Quality, and Advancing Care Information (ACI) performance categories. This alleviates the need for individual MIPS eligible

[1] 81 Fed. Reg. 28162 (May 9, 2016), *available at* https://www.gpo.gov/fdsys/pkg/FR-2016-05-09/pdf/2016-10032.pdf.
[2] Social Security Act (SSA) § 1848(q)(1)(E); SSA § 1848(q)(5)(B)(ii)(l).

clinicians and groups to use a separate mechanism to report data for these performance categories. However, the Coalition is against ***requiring*** QCDRs to report data for the CPIA and ACI categories because many QCDRs do not have the capabilities or resources to report the necessary data.

The Coalition also appreciates CMS's support of QCDRs as a means of enabling specialists to report on the measures most relevant to their practice. However, we have concerns about CMS's language under the proposed 42 C.F.R. § 414.1400(d) that would allow entities that do not meet the QCDR requirements on their own to collaborate with external organizations to qualify as a QCDR.[3] We assume CMS is trying, through this provision, to address the situation where a clinician-led professional organization may need to partner with a database vendor or other similar entity to meet the QCDR requirements. We are concerned, however, that the language of this provision is so broad that it would allow health information technology (HIT) vendors and other commercial entities to become QCDRs without any participation of clinician-led professional organizations that are focused on quality improvement relating to specific medical procedures, conditions, or diseases. Therefore, CMS's language could have the unintended effect of impeding the development of specialty-wide or procedure/disease-based registries. We ask that CMS clarify that QCDRs that involve multiple organizations must be led and controlled by clinician-led professional organizations or similar entities that are focused on quality improvement relating to particular types of medical procedures, conditions, or diseases. This language should not adversely affect HIT vendors, which have numerous other ways in which they can submit MIPS data to CMS on behalf of eligible clinicians.

In addition, the Coalition is also concerned that CMS chose to incorporate some proposals that limit the broader use of registries. CMS should support the use of QCDRs and other clinical outcomes data registries as data collection platforms that easily allow for benchmarking, linking measurement to performance, and tracking quality of care improvements.

The Coalition's specific comments focus on how the Proposed Rule can be modified to further encourage the use of QCDRs and other clinical outcomes data registries. In addition to the above comments, we urge CMS to implement the following changes to the Proposed Rule:

1) in the CPIA performance category, assign all registry-related CPIAs a high weight and apply CPIAs to other clinical outcomes data registries;

2) in the Quality performance category, clarify that QCDRs can license their non-MIPS quality measures to other QCDRs; remove the requirement that QCDRs submit one cross-cutting measure; include bonus points for QCDR submission mechanisms; suspend penalties for failure to meet benchmarks of first year measures and allow for a three-year

[3] 81 Fed. Reg. at 28285 ("We propose to allow that an entity that uses an external organization for purposes of data collection, calculation, or transmission may meet the definition of a QCDR provided the entity has a signed, written agreement that specifically details the relationship and responsibilities of the entity with the external organization effective as of September 1 the year prior to the year for which the entity seeks to become a QCDR (for example, September 1, 2016, to be eligible to participate for purposes of the 2017 performance period")).

period of automatic measure approval through the QCDR self-nomination process; retain reporting of measures groups and maintain the current 50% reporting threshold; and clarify quality data submission standards; and

3) in the ACI category, increase the bonus points for the registry measures; allow electronic QCDR participation to provide full ACI credit; and permit clinicians to attest to their performance.

1. The Clinical Practice Improvement Activities (CPIAs) Performance Category Should Give Greater Weight for Registry-Related Measures and Apply CPIAs to Clinical Outcomes Data Registries

While the Coalition supports CMS's proposal to allow eligible clinicians to submit data, engage in activities, or achieve objectives for the CPIA performance category through QCDRs, the Coalition strongly disagrees with CMS's proposed medium weight (10 points) for all but one of the registry-related CPIAs and also encourages CMS to expand the CPIA submission category to include other clinical outcomes data registries. While the Coalition understands CMS's justification for high weights (20 points) is based on alignment with CMS's national priorities and programs, registry-related CPIAs should be allocated a greater priority. The only registry-related CPIAs with a proposed high weight are the "use of a QCDR to generate regular feedback reports that summarize local practice patterns and treatment outcomes, including for vulnerable populations"[4] and "use of a registry or certified health information technology functionality to support active care management and outreach for patients" in treatment for behavioral health needs, dementia, and poorly controlled behavioral health conditions.[5]

The Proposed Rule assigns medium weights to all other registry-related CPIAs, such as those that involve participation in a QCDR for quality improvement, to demonstrate performance of activities that promote implementation of shared clinical decision making capabilities, to promote use of patient engagement tools, and for those ongoing practice assessment and improvements in patient safety.[6] By assigning registry-related CPIAs a high weight, CMS will incentivize increased participation and use of QCDRs because clinicians will more easily be able to achieve full points for the CPIA category.

In addition, the majority of registry-related CPIAs apply only to QCDRs and do not apply to other types of registries. For example, of the fifteen CPIAs that apply to QCDRs, only three CPIAs also apply to qualified registries.[7] The Coalition urges CMS to apply the QCDR CPIAs to other types of clinical outcomes data registries. Many organizations that run QCDRs have other non-QCDR clinical data outcomes registries that should be recognized as improving clinical practice. CMS is discouraging the use of other registries by only creating a few CPIAs that can be reported through non-QCDR registries. For purposes of identifying other kinds of

[4] *Id*. at 28573.
[5] *Id*. at 28585.
[6] *Id*. at 28570-86.
[7] *Id*. at 28573, 28581, 28585.

clinical outcomes data registries, we recommend that CMS adopt the definition of Clinician Led Clinical Data Registry that the Senate Health, Education, Labor, and Pensions Committee adopted in its Health IT Bill.[8]

2. CMS Should Modify the Quality Performance Category to Create Greater Incentives for Registry Reporting

The Coalition urges CMS to adopt several changes to greater incentivize the use of QCDRs to report measures in the Quality performance category.

A. The Coalition Recommends Sharing Measures Between QCDRs

The Proposed Rule at 42 C.F.R. § 414.1400(f) requires QCDRs to provide specifications for each measure, activity, or objective the QCDR intends to submit to CMS and receive CMS approval in order to use such measures. The Proposed Rule allows QCDRs to use measures not contained within the list of MIPS quality measures or alter MIPS quality measures, otherwise known as non-MIPS quality measures or "home-grown measures." The Coalition strongly agrees that QCDRs should have the flexibility to develop their own measures because the success of QCDRs rests on their ability to incorporate customized outcomes measures for each particular specialty. However, in the preamble discussing this requirement, CMS states that for approved non-MIPS quality measures, each measure "will be assigned a unique ID which can only be used by the QCDR that proposed it."[9]

While this rule is not contained within the regulation itself, the Coalition is concerned that prohibiting the sharing of non-MIPS quality measures between QCDRs will inhibit the efficient and cost-effective use and dissemination of such measures. The development and use of CMS-approved and successful home-grown quality measures is a time-consuming and expensive process. Allowing QCDRs to share their non-MIPS quality measures will permit the QCDR that develops a measure to recoup some of its costs while also expanding the number of physicians reporting on those measures, thus enhancing the ability of QCDRs and CMS to detect and analyze patterns in the QCDR data on home-grown measures. CMS may have issued this restriction due to concern about the unauthorized use of non-MIPS quality measures, but QCDRs can contract around this concern, through licensing agreements and other types of arrangements. Thus, the Coalition supports the ability of QCDRs to share their approved measures with other QCDRs, with or without a reasonable royalty or fee, when appropriate agreements between QCDRs exist.

[8] Improving Health Information Technology Act, S. 2511, 114th Cong. (as passed by S. Health, Educ., Labor, and Pensions Comm., Feb. 8, 2016).
[9] 81 Fed. Reg. at 28195.

B. The Coalition Recommends the Removal of the Cross-Cutting Measure Requirement and Increased Notice for Mandatory QCDR Structural Changes

The proposal requiring QCDR submission of cross-cutting measures creates additional barriers for the use of QCDRs. According to the Proposed Rule, 42 C.F.R. § 414.1335(a)(1)(i), providers submitting data through a QCDR must report on at least six measures, including one cross-cutting measure (if patient-facing) and at least one outcome measure, if available.[10] Requiring QCDRs to report on cross-cutting measures may not be relevant or applicable to the data that some QCDRs were designed to collect. Cross-cutting measures, such as Physician Quality Reporting System (PQRS) #128 (Preventative Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan) and PQRS # 226 (Preventative Care and Screening: Tobacco Use: Screening and Cessation Intervention) generally relate to preventative care. As many QCDRs are specialty and procedure-specific, requiring them to collect data on a cross-cutting measure is likely to force QCDRs to focus on health care areas that are outside of their core area of data collection and analysis.

In addition, Congress did not intend for clinicians to utilize QCDRs to submit traditional process measures. The Taxpayer Act of 2012 requires the Secretary of HHS to allow individual providers to submit measures via an approved QCDR as an alternative to traditional PQRS measures.[11] Under MACRA, the Secretary must establish an annual final list of quality measures from which MIPS eligible clinicians must choose the measures they will report.[12] The final annual list can include measures endorsed by a consensus-based entity, measures developed by the Secretary's draft quality measures plan, and measures submitted by stakeholders.[13] Any measure selected for inclusion in the annual list that is not endorsed by a consensus-based entity must have a focus that is evidence based.[14] New measures must also be submitted for publication to a specialty-appropriate peer-reviewed journal, which must include the method for developing and selecting the measure.[15] Measures used by QCDRs are exempt from the above requirements.[16] Together, the Taxpayer Act of 2012 and these exceptions reflect a congressional intent to allow specialties to develop and select QCDR measures outside the prescriptive process used to develop and select general quality reporting measures. The cross-cutting measures requirement is inconsistent with this legislative intent.

The Proposed Rule also states that QCDRs that desire to use a non-MIPS measure must go through a rigorous approval process to ensure the measures are meaningful for the specialty and

[10] If an applicable outcome measure is not available, the Proposed Rule requires MIPS eligible clinicians or groups to report one other high priority measure (appropriate use, patient safety, efficiency, patient experience, or care coordination measures). If fewer than six measures apply to the MIPS eligible clinician or group, the Proposed Rule requires the clinician or group to report on each measure that is applicable. *See* the Proposed Rule, 42 C.F.R. § 414.1335(a)(1)(i).
[11] American Taxpayer Act of 2012, amending SSA § 1848(m)(3).
[12] SSA § 1848(q)(2)(D)(i).
[13] *Id*. § 1848(q)(2)(D)(v).
[14] *Id*.
[15] *Id*. § 1848(q)(2)(D)(iv).
[16] *Id*. § 1848(q)(2)(D)(vi).

are rooted in science and the medical literature. CMS's proposal to include a cross-cutting measure is inconsistent with this rigorous review standard for other non-MIPS QCDR measures, which is necessary to ensure each measure is appropriate for a particular QCDR.

The requirement also poses significant operational and financial challenges for QCDRs, as the adoption of any new measures requires significant resources and time to incorporate into the QCDR. Many QCDRs do not have the functionality to report cross-cutting measures, including the ability to collect the necessary data elements for those measures. The current PQRS measure numerators and denominators are based on encounter codes, but many QCDRs are not able to collect these codes. Instead, QCDRs utilize measures from their particular clinical data fields. Thus, if the cross-cutting measure requirement is retained, QCDRs would need ample notice to comply with this structural change in the quality reporting process. These changes cannot realistically be adopted by the 2017 performance period.

The Proposed Rule also increases the burden on QCDRs by reducing the number of cross-cutting measure options for 2017 reporting compared to those available for 2016 reporting under the PQRS.[17] CMS proposes removing thirteen cross-cutting measures from the 2017 reporting period, which include measures such as PQRS #001 (Diabetes: Hemoglobin A1c Poor Control); PQRS #046 (Medication Reconciliation Post Discharge); PQRS #131 (Pain Assessment and Follow-Up); PQRS #155 (Falls: Plan of Care); PQRS #182 (Functional Outcome Assessment); and PQRS #400 (One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk). The Coalition is concerned that the ten remaining cross-cutting measures available for submission by QCDRs are too limiting and will further require QCDRs to dedicate some of their limited resources to collecting data that are not germane to their mission simply to fulfill the cross-cutting measure requirement. Therefore, if CMS insists on requiring QCDRs to report a cross-cutting measure, the Coalition requests that CMS provide a broader selection of measures. However, the Coalition's much preferred outcome would be for CMS to remove the requirement that MIPS eligible clinicians reporting in the Quality performance category via QCDRs report on one cross-cutting measure.

C. All MIPS Eligible Clinicians Utilizing a QCDR Should be Eligible for a Bonus Point for Reporting Quality Measures, Regardless of CEHRT Usage

The Proposed Rule at 42 C.F.R. § 411.1380(a)(1)(i) awards bonus points for reporting specific types of measures and using CEHRT systems to capture and report quality measures. The preamble states that QCDRs that obtain data from a clinician's CEHRT qualify for the bonus point.[18] While we support this proposal to offer bonus points to MIPS participants using a QCDR that obtains data from a clinician's CEHRT to report quality measures, we ask CMS to clarify that non-MIPS QCDR measures reported in the same manner would also earn the bonus point. We are also concerned that the Proposed Rule does not award bonus points for QCDR reporting without CEHRT. While the Coalition commends CMS for including bonus points for

[17] 81 Fed. Reg. at 28196.
[18] *Id*. at 28256.

the electronic transmission of measures through CEHRT, not all QCDRs have the capability to connect with a federally-certified EHR. Many QCDRs are not technologically aligned with CEHRT and some are unable to obtain data from CEHRT in accordance with CMS requirements. Therefore, in order to increase the use of registry reporting, the Coalition believes all clinicians utilizing a QCDR should be eligible for a bonus point in the Quality performance category, even if they don't use CEHRT.

D. CMS Should Suspend Penalties for First Year Measures and Allow a Three-Year Period of Automatic Measure Approval Through the QCDR Self-Nomination Process

The Coalition also disagrees with CMS's proposal for developing benchmarks for quality measures without baseline period information, such as new measures, based on data that are collected in the first performance year.[19] The Coalition is concerned that during the first performance year, clinicians will be blind as to the standards they must meet, and QCDRs will be particularly affected because they regularly introduce new quality measures each year. The Coalition requests that if the benchmark for a measure can only be established based on the first performance year, clinicians who do not meet the benchmark should not be penalized during the first performance year.

The Coalition also requests flexibility for measures initially approved in the QCDR self-nomination process. When a QCDR is forming, it typically partners with a number of vendors that code and develop software updates to facilitate reporting. These vendors often require 9-12 months to update data elements in order to report new measures. In addition, the implementation of new measures requires training for the staff of MIPS eligible clinicians on how to enter new data and integrate the new measures into the practice workflow. We ask that CMS consider modifying the QCDR self-nomination process to allow measures that have been approved in prior years to receive automatic approval for a period of three years. This three-year period would give QCDR vendors and MIPS eligible clinicians the necessary time to develop the technical and logistical requirements for collecting these new measures.

E. CMS Should Reinstate Reporting Measures Groups and the 50% Reporting Threshold

The Coalition has concerns about CMS's proposal to remove measures groups from the Quality performance category.[20] Physicians at small practices without an EHR will struggle to successfully report quality measures without measure groups because they lack the resources to submit the necessary data for multiple individual measures and can expend fewer resources on submitting through a measures group. The Coalition would like CMS to reinstate measure groups as a reporting option to help small practices. In addition, the Coalition recommends that both QCDRs and qualified registries should have the ability to report on measure groups.

[19] *Id*. at 28251.
[20] *Id*. at 28525-26.

Further, the Proposed Rule at 42 C.F.R. § 414.1340(a) requires MIPS eligible clinicians and groups submitting quality measures data through a QCDR, qualified registry, or EHR submission mechanisms to report data on at least 90% of their patients that meet the measure's denominator criteria, regardless of payer. Under the PQRS reporting mechanism, eligible professionals submitting data through these mechanisms only had to submit data on 50% of their patients. The Coalition views the reporting threshold increase from 50% to 90% as very harsh and burdensome on MIPS eligible clinicians and believes the threshold will create a barrier to the use of QCDRs and incentivize the use of other submission mechanisms that require reporting on a smaller percentage of patients.

The 90% requirement places the largest burden on eligible clinicians without an EHR, as it will require a significant increase in resources for collecting all the information to successfully report the necessary data. The Coalition requests that CMS return the reporting threshold to 50% for QCDR, qualified registry, and EHR submission mechanisms to avoid discouraging use of these activities. Or alternatively, the Coalition requests that CMS consider using other reporting options that do not involve collecting data from a certain percentage of patients, such as requiring physicians to report on a certain number of consecutive patients. The consecutive case approach could minimize the reporting burden while allowing for the collection of information to assess performance.

F. The Coalition Requests Clarification on Quality Data Submission Standards

The Coalition strongly supports QCDRs' ability to utilize both the Quality Reporting Document Architecture (QRDA) and XML file to submit quality measures. The Coalition seeks clarification on whether QCDR quality data can be submitted through the QRDA standard. The preamble to the Proposed Rule states that clinicians must comply with a "CMS-specified secure method for data submission, such as submitting the QCDR's data in an XML file,"[21] but does not contain any commentary on whether the QRDA standard is appropriate for QCDR use. As QCDRs must currently submit EHR-specified measures (eCQMs) using the QRDA standard, the Coalition also requests clarification on whether QCDRs can report eCQMs. Further, we ask for clarification on whether QCDRs can report non-MIPS measures using the XML format, and when the data for those measures are derived from an EHR and meet CMS' proposed end-to-end electronic reporting standard, that such measures could qualify reporters for the electronic reporting bonus point.

3. The Advancing Care Information Performance Category Should Give Greater Bonus Points for Participating in a Specialized Registry, Give Full Credit to Electronic Participation in a QCDR, and Allow Clinicians to Give Attestations

The Coalition is pleased that CMS is proposing at 42 C.F.R. § 414.1325 to allow MIPS eligible clinicians to submit ACI performance category data through QCDRs, qualified registries, and

[21] *Id*. at 28284.

CEHRT methods. However, the Coalition is concerned that CMS is only providing one bonus point for submission of the specialized registry measure. According to the Proposed Rule, 42 C.F.R. § 414.1380(b)(4)(i)(C), clinicians earn one bonus point for reporting any additional measures above the base score requirement for the Public Health and Clinical Data Registry objective. To earn points in the base score, CMS proposes that a clinician would need to complete submission on the Immunization Registry Reporting measure of the objective. The completion of any additional measure, such as Public Health Registry Reporting and Clinical Data Registry Reporting, under the objective would earn only one additional ACI bonus point.[22]

The Coalition urges CMS to make the optional Public Health Registry Reporting and Clinical Data Registry Reporting measure worth 10 bonus points. Many third-party submission mechanisms do not have the ability to report these measures, and QCDRs that can report these measures should be strongly rewarded to incentivize the further expansion of their capabilities. Awarding one bonus point is not enough incentive to reward registry participants or motivate non-registry participations to join their specialty's registry. Making registry reporting worth greater bonus points will encourage new participants to join registries and submit their data through these mechanisms. We also recommend that electronic participation in a QCDR should qualify for full credit under the ACI category, or at least full base score points.

CMS also proposes that QCDRs, qualified registries, and CEHRT have the option to submit data supporting ACI measures.[23] As acknowledged by CMS, before this Proposed Rule, the Medicare EHR Incentive Program allowed clinicians to attest to the numerators and denominators for certain objectives. Therefore, under the Proposed Rule, 2017 would be the first year that registries and CEHRT could submit EHR Incentive Program objectives and measures for the ACI performance category to CMS and the first time the data would be reported through the CMS Web Interface.[24] The Coalition agrees with CMS that QCDR submission of data for ACI measures should be an option. In fact, QCDR submission of ACI measures should never be a requirement. QCDRs are not currently able to submit this data and will have to spend an enormous amount of time and resources to develop the capability to submit this information. Devoting these resources may detract from other QCDR activities, such as measuring quality, encouraging practice improvement, and conducting research. By making submission optional, QCDRs that choose to do so can slowly expand their capabilities over time and submit data for ACI measures when they are ready. Therefore, the Coalition requests that QCDR submission of ACI measures remain optional for QCDRs now and in the future.

Conclusion

The Coalition appreciates this opportunity to comment on CMS's proposed regulations to implement MACRA and its special efforts to encourage the use of QCDRs in accordance with the statute. We strongly support the expansion of the use of QCDRs and other clinical outcomes data registries to help ease clinicians' burdens for submitting data under MIPS. While the

[22] *Id*. at 28228.
[23] *See* the Proposed Rule, 42 C.F.R. § 414.1325(a).
[24] 81 Fed. Reg. at 28219.

Coalition greatly appreciates CMS's efforts thus far, the additional changes described above will increase incentives to use third-party submission mechanisms and remove some proposals that would create barriers to the development of QCDRs in particular. We urge CMS to adopt the Coalition's suggested changes and continue to facilitate the use of QCDRs and other clinical outcomes data registries. These changes will allow the use of registries to grow and ultimately result in even greater improvements in the quality of patient care.

Thank you for the opportunity to submit these comments. If you have any questions, please contact Rob Portman at Powers Pyles Sutter & Verville PC (Rob.Portman@ppsv.com or (202)-872-6756).

Respectfully submitted,

AMERICAN ACADEMY OF DERMATOLOGY ASSOCIATION
AMERICAN ACADEMY OF OPHTHALMOLOGY
AMERICAN ACADEMY OF OTOLARYNGOLOGY- HEAD AND NECK SURGERY
AMERICAN ACADEMY OF PHYSICAL MEDICINE AND REHABILITATION
AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS/ NEUROPOINT ALLIANCE
AMERICAN COLLEGE OF EMERGENCY PHYSICIANS
AMERICAN COLLEGE OF GASTROENTEROLOGY/GIQUIC
AMERICAN COLLEGE OF RHEUMATOLOGY
AMERICAN COLLEGE OF SURGEONS
AMERICAN GASTROENTEROLOGICAL ASSOCIATION
AMERICAN JOINT REPLACEMENT REGISTRY
AMERICAN SOCIETY FOR GASTROINTESTINAL ENDOSCOPY/GIQUIC
AMERICAN SOCIETY FOR RADIATION ONCOLOGY
AMERICAN SOCIETY OF ANESTHESIOLOGISTS/AMERICAN QUALITY INSTITUTE
AMERICAN SOCIETY OF NUCLEAR CARDIOLOGY
AMERICAN SOCIETY OF PLASTIC SURGEONS
AMERICAN UROLOGICAL ASSOCIATION
NORTH AMERICAN SPINE SOCIETY
SOCIETY FOR VASCULAR SURGERY
SOCIETY OF INTERVENTIONAL RADIOLOGY
THE SOCIETY OF THORACIC SURGEONS