DERMASCIENCES
A TISSUE REGENERATION COMPANY

August 22, 2014

Via Electronic Submission

Ms. Liz Richter
Deputy Director, Center for Medicare
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1613-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted electronically: http://www.regulations.gov

RE: CMS -1612-P Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015.

Dear Director Richter,

Derma Sciences Corporation appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS") Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015, published in the Federal Register on July 11, 2014 (CMS-1612-P, Federal Register, Vol. 79, No. 133).

Derma Sciences is a tissue regeneration company focused on advanced wound and burn care. It offers a line of products with patented technologies to help better manage complex chronic and acute wounds which have difficulty healing such as diabetic foot ulcers, venous leg ulcers, pressure ulcers and burns.

As an industry leader in regenerative medicine, Derma Sciences is focused on ensuring that issues impacting the treatment of chronic wounds are given appropriate consideration in the formation of federal health care and reimbursement policy.

Recommendations
Derma Sciences respectfully requests that CMS consider and implement the following recommendations:

214 Carnegie Center, Suite 300, Princeton, NJ, 08540
P: 609-514-4744 **F:** 609-514-8554
www.dermasciences.com

DERMASCIENCES
A TISSUE REGENERATION COMPANY

- Finalize the following two new individual Quality Measures beginning in 2015:
    - Recurrence or amputation following endovascular infrainguinal lower extremity revascularization: Percentage of patients undergoing endovascular infrainguinal revascularization for non-limb threatening ischemia (claudication or asymptomatic) require repeat ipsilateral revascularization or any amputation within 1 year.
    - Recurrence or amputation following open infrainguinal lower extremity revascularization: Percentage of patients undergoing open infrainguinal revascularization for non-limb threatening ischemia (claudication or asymptomatic) require repeat ipsilateral revascularization or any amputation within 1 year.

- Finalize the proposed new quality measure Reporting by the Group Practice Reporting Option Web Interface beginning in 2015 and beyond:
    - Diabetes: Foot Exam: Percentage of patients aged 18-76 years of age with diabetes who had a foot exam during the measurement period.

- Finalize the proposed transition of all 10-day and 90-day global surgery codes to 0-day global periods only upon completion of comprehensive data analysis and addressing any inconsistencies in actual performance of post-operative visits within the existing global periods.

- Eliminate the proposed changes to Open Payment reporting requirements including :
    - Proposal to delete the Continuing Education Exclusion in its entirety;
    - Proposal to require the reporting of the marketed name of the related covered and non-covered drugs, devices, biologicals, or medical supplies.

<u>Quality Measures</u>

Recommendation: The Agency moves forward with the proposed quality measures which are associated with lower limb treatment including revascularization and foot exams. However, for the two measures which report on the recurrence or amputation following open or endovascular infrainguinal lower extremity revascularization, often times a conservative approach is taken with the intention of limiting the extent of amputation. This is done in an effort to preserve as much soft tissue and vascular and bony architecture as possible. The Agency should take this into consideration.

214 Carnegie Center, Suite 300, Princeton, NJ, 08540
P: 609-514-4744 **F:** 609-514-8554
www.dermasciences.com

DERMASCIENCES
A TISSUE REGENERATION COMPANY

Additionally, Derma Sciences commends the Agency for its awareness of the importance of foot exams for diabetic patients. Diabetic foot ulcers are a significant problem for Americans and can be avoided with a simple foot exam. Fifteen percent of patients with diabetes are at risk to develop a diabetic foot ulcer [National Diabetes Data Group: Diabetes in America, Vol. 2, Bethesda, MD, NIH 1995 (NIH publication number 95-1468)]. Diabetic foot ulcers often precede lower extremity amputations in diabetic patients; in fact according to data provided by AHRQ, for Medicare beneficiaries, between the years of 2006 to 2008, diabetic foot ulcers preceded lower extremity amputations in 85% of the time [www/ahrq.gov]. We support and request the proposal of these new quality measures move forward.

CPT® Procedure Coding Changes

We respectfully request the Agency proceed with caution with regards to the proposed transition of all 10-day and 90-day global surgery codes to 0-day global periods and only after an extensive data analysis, the results of which would be open and subject to the public notice and comment rule making process. This analysis should include Electronic Medical Record data sources from multiple geographically dispersed sites, and consecutive years to account for changes in practices with regards to post-operative care. Including multiple sources from various geographic locations will account for any changes in care due to access issues for Medicare beneficiaries.

Recommendation: The Agency considers extensive data analysis prior to implementing proposed transition of all 10-day and 90-day surgery codes to 0-day global periods. The results of the analysis should be subject to the public notice and comment rule making process.

Open Payment System

Continuing Education Exclusion

We respectfully oppose the proposal to delete the Continuing Education Exclusion in its entirety. We appreciate that the Agency wants to simplify the Continuing Education Exclusion and avoid redundancy in the current regulation. The requirement as defined in §403.904(g) provides sufficient oversight to protect against sharing of biased educational content. The proposed solution to have the exclusion reside under §403.904(i), adds a requirement that the manufacturer be "unaware" of the identity of the covered recipient 'during the reporting year or by the end of the second quarter of the following reporting year'. This is not a practical requirement in the age of the internet and interactive media. Knowing, or being told by the continuing education program organizer who is speaking (before, during, or after the event) is distinguishable from manufacturers requesting speakers or directing program content, and does not undercut the safeguards in place to qualify a program as CME [as currently defined in§403.904(g)].

214 Carnegie Center, Suite 300, Princeton, NJ, 08540
P: 609-514-4744 **F:** 609-514-8554
www.dermasciences.com

DERMASCIENCES
A TISSUE REGENERATION COMPANY

We believe the current standards are reasonable and appropriate to give the Agency and the public confidence the financial support provided to continuing education programs is provided in a manner that insulates speakers from any real or perceived influence by manufacturers. We appreciate the Agency's concern that providing a list of accrediting organizations may appear to be an apparent endorsement to the accrediting organizations. However eliminating the list of accrediting organizations would complicate the process, rather than meet the Agency's goal to simplify. If the list of accredited organizations was not provided, then CMS would need to define specifically program requirements and standards for accreditation.

Recommendation: We strongly encourage CMS to maintain §403.904(g), expand the list of accrediting bodies if additional entities meet the standards CMS applied to those currently listed, and include a clear disclaimer with respect to their listing being an endorsement.

Reporting Requirements

The proposal to require manufacturers to report marketed name of the related covered and non-covered drugs, devices, biologicals or medical supplies is an administrative burden for manufacturers. Often clinicians are selected to speak on their experience in a therapeutic area, using multiple products, often in combination in their clinical practice. Not all of the products are from a single manufacturer. For example, Derma Sciences engages physician thought leaders on wound healing. During their presentations often they reference several products in the therapeutic area, some of which are not manufactured by Derma Sciences. Therefore the proposed change to require all products be reported, would be an onerous task, requiring additional time and resources.

We agree and support the agency's objective to ensure that the reported information the public receives is meaningful to it. We believe providing the product category or therapeutic area is more meaningful to the public than simply the brand names. Additionally this would be administratively burdensome to alter the current system in place. The system would need to be modified to meet the proposed reporting changes.

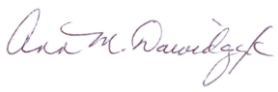
Recommendation: We request the Agency maintain the current reporting structure for manufacturers to report therapeutic area or product category of related drugs, devices, biologicals or medical supplies.

214 Carnegie Center, Suite 300, Princeton, NJ, 08540
P: 609-514-4744 **F:** 609-514-8554
www.dermasciences.com

DERMASCIENCES
A TISSUE REGENERATION COMPANY

Derma Sciences appreciates the opportunity to provide comments during this proposed rule period. Should you have any questions or need additional information, please do not hesitate to contact me at 508-842-3972 or via email at adawidczyk@dermasciences.com.

Sincerely,



Ann Marie Dawidczyk
Director, Health Policy & Reimbursement

cc: Viviane Guay, VP Health Policy & Reimbursement

214 Carnegie Center, Suite 300, Princeton, NJ, 08540
P: 609-514-4744 **F:** 609-514-8554
www.dermasciences.com