



*American Journal of Respiratory  
and Critical Care Medicine®*

*American Journal of Respiratory  
Cell and Molecular Biology®*

*Proceedings of the American  
Thoracic Society®*

*We help the world breathe®*

PULMONARY • CRITICAL CARE • SLEEP

STEPHEN C. CRANE, PhD, MPH  
Executive Director

GARY EWART  
Director  
Government Relations

FRAN DU MELLE  
Director  
International Activities

Washington Office  
1150 18th Street, N.W.  
Suite 300  
Washington, D.C. 20036-3816  
P. (202) 296 - 9770  
F. (202) 296 - 9776  
[www.thoracic.org](http://www.thoracic.org)

NICHOLAS S. HILL, MD  
President

MONICA KRAFT, MD  
President-Elect

DEAN E. SCHRAUFNAGEL, MD  
Immediate Past President

PATRICIA W. FINN, MD  
Vice President

THOMAS W. FERKOL, MD  
Secretary-Treasurer

National Headquarters  
25 Broadway, 18th Floor  
New York, NY 10004  
P. (212) 315 - 8600  
F. (212) 315 - 6498

February 17, 2012

Marilyn Tavenner, Acting Administrator  
Center for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-5060-P  
P.O. Box 8013  
Baltimore, MD 21244-8013

Dear Acting Administrator Tavenner,

On behalf of the 15,000 members of the American Thoracic Society, I want to express my appreciation for the opportunity to comment on the proposed rules for implementation of section 6002 of the Affordable Care Act (ACA) – frequently referred to as the Physician Payment Sunshine provision. As a medical professional society representing physicians, researchers and allied health professionals dedicated to the prevention, detection, treatment and cure of pulmonary, critical care illnesses and sleep disorders, the American Thoracic Society is keenly interested in how the Physician Sunshine reporting provisions will impact our members, relations between industry and medical professional societies and the patients we ultimately all serve.

### **Commitment to Physician Sunshine Goals and Physician-Industry Collaboration**

The ATS strongly supports the underlying legislation's objectives to ensure appropriate levels of transparency, balance and scientific rigor in physician-industry interaction. We make extensive efforts annually to meet Accreditation Council for Continuing Medical Education (ACCME) and Council of Medical Specialty Societies (CMSS) standards.

At the same time, the ATS considers collaboration among physicians, professional medical societies, academia, government and industry to be crucial to our mission of improving treatments and finding cures for patients. We are greatly concerned that several of the proposed reporting requirements will affect professional societies' educational mission in a

**ATS 2012 • International Conference • May 18 - 23 • San Francisco • California**

manner that will impair this collaboration and make achieving our mission more difficult and expensive for everyone. None of these unintended consequences are in keeping with the spirit of the underlying legislation.

### **Defining “Transfer of Value”**

Both section 6002 of the Affordable Care Act and the proposed implementing regulations describe what constitutes a transfer of value. The proposed rule offers a brief discussion of what constitutes a “payment or other transfer of value” saying, that it is

...defined broadly in section 1128G(e)(10)(A) of the Act as “a transfer of anything of value.” This includes all payments or other transfers of value given to a covered recipient, regardless of whether the covered recipient specifically requested the payment or other transfer of value.

While this discussion suffices to describe the spirit of the underlying legislation, the proposed rule leaves unanswered a number of real world practical applications that need to be addressed. One of the most pressing unanswered questions is whether industry support of independent educational sessions provided through grants from industry to our Society, whether accredited or not, constitutes a transfer of value from industry to a covered recipient in attendance at the educational session, or larger meeting.

The American Thoracic Society believes strongly that industry support of educational sessions DOES NOT constitute a transfer of value from industry to a covered recipient. We offer the following background information and two scenarios to illustrate both the questions surrounding this issue and the rationale for our position.

### **Background – How American Thoracic Society Education Sessions are Developed**

The ATS, like many medical professional societies, provides educational sessions at its annual conference and other meetings that we hold. The content of these educational sessions, including the topic matter, content and speakers, is entirely independent; it is determined solely by the members of the American Thoracic Society. Every year proposed educational sessions are submitted by ATS members to the International Conference Planning Committee. They are then peer reviewed and are accepted or rejected based on a variety of factors including clinical relevance, scientific content, new information on the topic and expected interest from meeting attendees. Consistent with Accreditation Council for Continuing Medical Education requirements, industry marketing personnel are not involved in course selection, planning or delivery.

Each session has a chair, who is responsible for reviewing conflict of interest disclosure information gathered by the Society in advance of the conference, disclosing conflict information and, when warranted, working with the ATS International Conference Committee and ATS Ethics and Conflict of Interest Committee to manage and/or resolve any cases where the disclosed potential conflict of interest might unduly prejudice a proposed speaker.

Speaker disclosures are also made available to learners (session attendees) online, and each speaker shows a slide summarizing his/her disclosure at the start of his/her presentation.

In short, the ATS goes to great lengths to meet and exceed the ACCME and CMSS standards that are designed to ensure that the content of sessions is not influenced by industry for its commercial purposes.

### **Industry Support for Educational Sessions**

After the educational sessions at the American Thoracic Society International Conference have been programmed by the International Conference Committee, the ATS does submit requests to industry for educational grant support, mostly through web portals. In compliance with the ACCME Standards for Commercial Support, the ATS provides learners with appropriate attribution of all grant support, whether commercial, from other societies, or from federal agencies, through listings in the Final Program and signage outside the room.

Course chairs and speakers have no input or interaction with ATS or with industry regarding which educational offerings are submitted for consideration of industry support, nor do they have any knowledge of the level of support provided to selected educational sessions. The letters of agreement signed for all educational grants clearly state the relationship is between the granting organization and the American Thoracic Society.

### **Why Professional Societies Accept Industry Support for Educational Sessions**

Professional societies like ours seek and accept industry support of education sessions to expand our educational reach. The ATS is a 501(c)(3) medical professional society, whose mission is to improve health worldwide by advancing, clinical care and public health in pulmonary disease, critical illness and sleep disorders through research, education and advocacy. Education is a crucial part of the ATS mission but developing high quality educational programming has a significant cost. The educational grant support professional associations like the ATS receive from industry permits a wider range of educational programming where registration costs alone would not cover the costs of development.

For instance, sessions on rare and unusual health conditions that are important scientifically may not generate enough revenue to offset the cost of development. Industry support also allows the ATS to expand the impact of its educational offerings through webcasts, podcasts, and other online resources to ensure educational materials reach as wide an audience as possible. Without industry support, the ATS and other medical societies would be severely limited in their mission to share important clinical and research information on pulmonary, critical care and sleep disorders with the medical professional community and patients,

### **How the Concept of Transfer of Value Affects These Scenarios: Session Speakers**

Below are two real world examples of educational sessions offered by the ATS. Comparing and contrasting Scenario A and B raises a number of questions related to Sunshine reporting that we hope the Secretary will address in the final rule.

### Scenario A

A physician proposes an educational session to update attendees on the latest clinical advances in the detection, diagnosis and management of chronic obstructive pulmonary disease (COPD). Five speakers are selected, all of whom are free of industry or other relevant conflicts. Industry is not involved in the topic selection, course content or speaker selection. The course is reviewed and approved by the International Conference planning committee. The five speakers agree to speak for the ATS at this educational session. After the course is programmed, the ATS submits several educational grant requests for consideration to pharmaceutical companies that make COPD-related treatments to support the course. Two companies agree to support the course with educational grants that are consistent with the ACCME Standards for Commercial Support. The ATS signs Letters of Agreement that state that the relationship defined by the educational grants grant is between the company and the American Thoracic Society. The course is attended by 60 people. The course speakers each receive a \$500.00 honorarium from the American Thoracic Society for their participation as faculty in the course.

### Scenario B

A physician proposes an educational session to update attendees on the latest clinical advances in the detection, diagnosis and management of pulmonary fibrosis. Five speakers are selected, all of whom are free of industry or other relevant conflicts. Industry is not involved in the topic selection, course content or speaker selection. The course is reviewed and approved by the International Conference planning committee. The five speakers agree to speak for the ATS at this educational session. After the course is programmed, the ATS submits several educational grant requests for consideration to pharmaceutical companies that have an interest in pulmonary fibrosis treatments to support the course. Industry declines the offer to support the course. The course is attended by 60 people. The course speakers each receive a \$500.00 honorarium, again from the American Thoracic Society, for their participation as faculty in the course.

**Was There A Transfer of Value?** – Clearly, the honorarium paid to the speaker in Scenario B does not count as a “transfer of value” as industry did not provide any monetary support to the ATS or the speakers for convening the course. Reporting requirements would not apply in Scenario B. However, does the honorarium payment to a speaker in Scenario A count as a transfer of value and therefore trigger a Sunshine report? An aggressive interpretation of section 6002 might require reporting for the honorarium payment in Scenario A, with the Society as a “third party”. We believe such an aggressive interpretation would not be in keeping with the spirit of 6002.

**ATS is the recipient of the value transfer** - In the case of industry-supported educational sessions, the “transfer of value” takes places between industry and the American Thoracic Society (ATS). The ATS receives the industry funds and has full discretion on how those funds are used. In short, the ATS is the full and total recipient of the value of industry support for educational sessions. The ATS, in turn, provides educational value to the attendees of the session.

**No “Transfer of Value” Between Industry and Covered Recipient Takes Place.**

Similarly, no “transfer of value” takes place between industry and the covered recipient in either of these scenarios. Speakers in both scenarios receive the same payment, so measurable monetary value is associated with speaking at an industry-supported event. Further, speaking at an industry-supported event confers no other “value transfer” covered in the proposed rule. As such, we believe strongly that no transfer value between industry and the session speaker has taken place, and therefore physician Sunshine reporting requirements do not apply.

We believe our interpretation of the value transfer in this case is consistent with the letter and the spirit of the underlying legislation.

**How the Concept of Transfer of Value Affects These Scenarios: Session Attendees**

A similar set of questions arises for the attendees of Scenario A and Scenario B. Clearly, attending a session in Scenario B does not require Sunshine reporting. Does attending the educational session described in Scenario A require Sunshine reporting? We believe it does not. Again, we do not believe a transfer of value between industry and a covered recipient has taken place. In both Scenario A and Scenario B, the topics, content and speaker selection were independent of and uninfluenced by industry support. Industry support of session A did not change the content of the course, did not make the course better or add any tangible “value.” From the perspective of the attendee, industry support did not offer any added value. The transfer of value is with the ATS, not the session attendee. If no added value was provided to the attendee, then no transfer of value took place and physician payment Sunshine reporting requirements should not apply.

To further complicate this, let’s look at Scenario A and Scenario B as full-day post-graduate courses. Included in the program is a boxed lunch with soda, and two coffee breaks (am/pm). The cost of the food provided is the same in both scenarios, and the food is provided by the Society in both instances. Again, we believe this is not a transfer of value that would require Sunshine reporting. Any granting relationship is between the Society and the company, not the attendee and the company.

**Recommendation:** The ATS recommends that the Secretary explicitly state in the final rule that honorarium provided to speakers at professional society-developed educational sessions supported by educational or charitable grants DO NOT constitute transfers of value (and therefore are not reportable) provided that speakers do not seek industry support, are not involved in securing industry support and do not receive additional honorarium for participating in the session.

**Recommendation:** The ATS strongly recommends that HHS explicitly state that attending a professional society-developed, industry-supported educational session **(whether accredited or not) is not a transfer of value (and is therefore not reportable).**

Should the Secretary reject the ATS's position and instead determine that industry supported educational sessions do represent a transfer of value (for either honorarium payments or attending the course), application of the Sunshine reporting provisions becomes very complex and cumbersome and will likely lead to a swift end of industry-supported educational sessions. The Secretary will have to specify how to standardize calculations across all educational sessions and medical specialty societies of all scope and size, in a way that is applicable to all meeting sizes, so that a consistent measure of transferred value is recorded, taking into account the cost of the session development and execution, as well as the variable number of attendees who fit the definition of "covered recipient."

### **Can Honorarium Associated with Industry Support of Education Sessions Operate Under the 3<sup>rd</sup> Party Exclusion?**

At first glance, it may appear that educational sessions described in Scenario A could continue to operate under the 3<sup>rd</sup> party reporting exclusion, however applying the 3<sup>rd</sup> party exclusion in the real world is fraught with problems.

For example, the 3<sup>rd</sup> party exemption requires that industry be unaware of the recipients of the transfer of value. It is impossible for industry to be unaware of speakers at public meetings. The identity of speakers is public information. The speakers' names and titles are posted in all materials describing the course. There is no conceivable way that this information could be withheld from industry to prevent their learning the identity of course speakers.

### **Why does the status of industry-supported sessions honorarium matter?**

The American Thoracic Society is fearful that should the Secretary require reporting of honoraria associated with industry-supported educational sessions, it will have a chilling effect on the willingness of speakers to participate in educational sessions. Speakers participate in ATS educational sessions for a variety of reasons including: desire to share information, prestige associated with being a recognized expert, and academic and clinical advancement. They do not speak to gain industry favor. In fact, accepting direct industry funding is considered grounds for dismissal at some academic institutions.

### **Can Attending Industry-Supported Educational Sessions Operate Under the 3<sup>rd</sup> Party Exclusion?**

While the 3<sup>rd</sup> party exemption may have been drafted by Congress to address educational sessions supported by industry, the extreme steps needed to ensure the industry is "unaware" of the identity of attendees effectively makes this reporting exclusion unworkable.

The ATS does not share with industry the identity of people who attend ATS educational sessions. While technically it would be possible to identify individuals attending a particular session, this would be an expensive and onerous burden on both the Society and the attendee. For instance, would only partial value be ascribed if a person attended a session for only 10 minutes or part of the program?

Industry attendees make up approximately 10% of conference attendees and as conference attendees. They are entitled to participate in meeting activities, including attending educational sessions. Many are active members of the Society. Allowing clinicians and scientists to attend all sessions facilitates the free flow of information and ideas that is essential to scientific progress. We are fearful that unreasonable application of the Sunshine reporting provisions could impede such scientific progress and create additional barriers to the development and testing of newer, more effective drugs for patients.

For example, in Scenario A where the ATS is offering an industry-supported educational session on the latest advance in the diagnosis and management of COPD, 60 people attend. What if one of the attendees is an industry scientist who is interested in learning the latest advances in COPD care? While it is ridiculous to suggest that the industry scientist's primary goal is to record names of fellow attendees, that industry scientist will be aware of others in the room. Does having one industry member attending the meeting – primarily as a scientist seeking scientific information -- pierce the veil of “unaware of the identity?” What if someone from marketing is in the room? What if industry staff stands outside the room and makes notes of who walks in? Again we believe it is ridiculous to suggest that industry staff attend educational sessions to record who is in the room. However, under a strict interpretation of 3<sup>rd</sup> party reporting exemption, it would be impossible to claim that industry was unaware of who attended the meeting.

The steps needed to “protect” the identity of meeting attendees - banning conference attendees who are employed by industry from educational sessions, requiring industry staff to remain 100 feet from meeting room entrances – are extreme, impractical, likely ineffective and damaging to the educational process.

The implications for a poorly interpreted and poorly implemented Physician Payment Sunshine rule on scientific meetings and scientific progress are severe and are not in keeping with the spirit of the underlying legislation. The most effective way to prevent these unintended consequences is for the Secretary to determine that industry supported educational sessions – as described in Scenario A – do not constitute a transfer of value for speakers or attendees and therefore does not trigger reporting.

#### **Other Excluded Transfers**

The American Thoracic Society supports the list of excluded transfers in the proposed rules but improvement and clarifications are needed to ensure orderly implementation.

**Transfers of Value less than \$10** –We believe the exclusion of transfers of value less than \$10 is in keeping with the letter and spirit of the underlying legislation. While we appreciate the proposed exclusion, we note that these transfers, while not necessarily publicly reportable, will effectively become recorded events to ensure aggregate spending does not exceed the \$100 threshold. The record keeping for these non-reportable transfers will be extremely cumbersome for many entities including individuals and organizations such as our Society.

To make this exclusion truly workable, the ATS recommends either the transfer value be raised or the total transfer threshold be raised.

**Recommendation:** HHS should use its discretionary authority to develop a more workable reporting exemption for transfers of value less than \$10.

**Educational Materials** – the ATS believes this is an important exemption and seeks clarification from HHS on how they will interpret the definition of “educational materials.” We note that HHS is seeking input on what educational materials are not necessarily intended for patient use. The ATS believes strongly that reprints of peer reviewed articles meet the spirit of the educational material reporting exemption and should be explicitly included in HHS’s final rule.

Like many medical professional societies, the ATS produces peer-reviewed academic journals that publish original research articles and clinical practice statements. Many of these peer-reviewed articles update clinical practice recommendation for the diagnosis and management of clinical conditions or expand the available treatments options for treating clinical conditions. Frequently, companies that have products impacted by research articles or clinical practice statements purchase reprints of these articles for distribution to physician as educational material. In most cases, the reprints are intended to educate the physician on how to detect, diagnose, manage or cure a condition, and are not necessarily intended for patient use. We believe strongly that patients ultimately benefit from distribution of these peer-reviewed articles.

The ATS believes that reprints – as described above – meet the spirit of the “educational material exemption” and that distribution of reprints would qualify under the educational materials reporting exemption.

**Recommendation:** The ATS requests that HHS, in the final rule, explicitly state that reprints of peer reviewed articles intended for physician education meet the educational materials reporting exemption.

**Reportable Transfers: Research**

The ATS notes that both the authorizing legislation and the proposed rule include research as a reportable transfer. Further, the proposed rule requires that industry research grants to investigators at teaching hospitals be reported both as payments to the hospital and as payments to the investigator. We are concerned that this double-counting will provide misleading information to the public.

**Recommendation:** CMS should eliminate the requirement for double counting for research to teaching hospitals and investigators.



### **Reportable Transfers: Research**

We are further concerned that requiring the public reporting of research implies that research is somehow an inappropriate activity for physicians. We believe the Congress' intent was to capture transfers that might give patients information to judge the impartiality of a specific physician and Congress included the reporting of research to prevent industry and physicians from "hiding" such transactions under the guise of research. However, the majority of the research supported by industry is extensively reviewed and approved by institutional review boards (IRBs), and provides valuable basic science and clinical information. We think CMS should consider limiting what types of research are reportable. We would urge CMS to consider exempting the reporting of research for those projects that have received human subjects approval from IRBs and/or are administered by the researcher's institution without direct payments going to the scientist.

**Recommendation:** Research that has received human subjects approval from an IRB and/or is administered by the researcher's institution should be exempted from reporting.

### **Timeliness of the Proposed Rule and Initial Year Implementation Challenges**

The ATS is concerned that the proposed rules were issued much later than expected and are now too late to be appropriately implemented in calendar year 2012. As noted in our extensive comments above, significant issues on what constitutes a transfer of value are yet to be clarified. How these issues are clarified and resolved will have a significant impact on many medical professional societies, industry partners and physicians. While we appreciate the extreme pressure HHS staff has been under to complete the wide range of implementation regulations called for by the ACA, late promulgation and finalization of these rules will complicate the initial year collection and reporting of data. The data systems that will be relied on to provide much of the information called for in the final rule cannot be quickly, easily, or cheaply revised. The ATS and many societies like us will not have the necessary lead time and resources to make changes in our data system to comply with reporting requirements in 2012.

As an example, registration for the ATS International Conference, held the third week in May each year, opens December 1<sup>st</sup> – almost five months ahead of the meeting. Building the registration portal for an International Conference that will capture National Provider Identifiers for US Clinical Attendees only is a complicated, time-consuming and expensive process. Industry inevitably will come to rely on information captured in the registration process, as it is also provided in lead retrieval when a physician visits the Exhibit Hall. We hope the Secretary will be mindful of these implementation challenges during the initial implementation phase.

### **Conclusion**

We hope these comments are helpful in the Secretary's determination of the final rules for implementing the Physician Payment Sunshine provision. We hope the Secretary will agree with our position on industry grant support for educational sessions and explicitly determine

that such support constitutes a transfer of value between industry and the recipient medical professional society – and not a transfer of value to an educational speaker or course attendee.

We are greatly concerned that any other interpretation will create an unworkable reporting system that will reduce educational offerings, impede the free flow of clinical and scientific information between industry and the medical professional community and ultimately retard the progress of education and science. None of these unintended consequences are in keeping with the spirit of the underlying legislation.

Sincerely,

A handwritten signature in black ink that reads "NS Hill". The letters are cursive and somewhat stylized.

Nicholas S Hill MD

President

American Thoracic Society