Reprints at the Dawn of the 'Sunshine Act'

New Formats and Reporting Implications
Executive Summary

Under the Physician Payments Sunshine Act, payments to physicians by pharmaceutical and other companies must be publicly reported. That requirement extends to journal article reprints—long seen as an educational and marketing tool for use with health care professionals (HCPs). But that doesn’t mean that reprints are no longer of value. Rather, with a shrinking pharma sales force and HCPs’ increasing reliance on digital formats for clinical information, reprints are more valuable than ever.

Wolters Kluwer Health (WKH) offers a number of new reprint formats, facilitating effective communication of essential research evidence to HCPs at a time when it’s harder than ever to connect directly to them. These include new “View-Only” electronic reprint (ePrint) formats that users read on-screen only, reprints embedded into physician face-to-face detailing aids, and ePrint distribution integrated into e-marketing such as digital advertising and email.

In this white paper, we discuss the Sunshine Act reporting requirements for various reprint formats. Since there is no “transfer of value,” View-Only ePrints are exempt from reporting. In contrast, “Downloadable/Printable” ePrint formats do represent a transfer of value. They may need to be reported, depending on the circumstances under which they are distributed.

The Sunshine Act rules and regulations are still evolving, and are subject to differing interpretations. This white paper seeks to help “demystify” the requirements for reporting of journal reprints under the Sunshine Act. It also introduces the new reprint/ePrint formats, discusses reporting implications for each, and outlines factors to consider in choosing between formats.

More than ever, reprints and ePrints can be an invaluable strategic tool, providing HCPs with peer-reviewed journal articles—their preferred source of clinical information—to communicate highest-level evidence on product benefits.
If you’re a pharma or medical device marketer, you hardly need a white paper to tell you these are challenging times. The universe of prescribers has increased steadily, including a twofold increase in the number of physicians over the past three decades. Meanwhile, sales forces have been downsized, leaving fewer reps in the field. Those reps still out there are finding fewer opportunities to talk to prescribers about new products and indications that can improve patient health.

And now comes the Physician Payments Sunshine Act, part of the Patient Protection and Affordable Care Act. Under the Sunshine Act, pharma and medical device manufacturers (among others) are required to report “payments or other transfers of value” to physicians and teaching hospitals to the Centers for Medicare & Medicaid Services (CMS).

How do you get your clinical message in front of the right health care professional at the right time?

The Sunshine Act adds yet another challenge to meeting that critical goal. Marketers need to invest their resources wisely, while giving prescribers accurate and convincing evidence of product safety and efficacy.

One of the most effective tools for meeting that challenge is also one of the oldest—commercial reprints of clinical trials, reviews and other journal content. Journal reprints provide the scientific evidence that establishes your product’s benefits. Along with clinical experience, it’s the information on which HCPs base their recommendations for the patients they see every day.

In this White Paper, you will:

- Learn about the unique strategic value of reprints at a time of narrowing options for connecting with prescribers.
- Become familiar with Sunshine Act rules on reprints and other educational materials, including criteria governing which types may and may not need to be reported.
- Learn about new ePrint formats including “View-Only” formats, which can be exempt from reporting, and “Printable/Downloadable” formats, which are reportable in some situations but exempt in others.
- Discover new and emerging channels for sharing peer-reviewed evidence supporting clinical decision-making, including options for distributing ePrints inside electronic detailing aids and via journal target audiences.

“Here Comes the Sun”—Reporting Is Now a Reality

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Reprints Are Reportable

Obviously, handing physicians a journal article reprint is a lot different from giving them a pen or picking up the tab for lunch! But like other types of educational materials, reprints may be considered reportable under the Sunshine Act.

Materials intended for the direct benefit of patients are exempt from reporting requirements. For example, an anatomical chart or model used in patient teaching does not need to be reported.

Of course, educational materials that provide the doctor with clinical information will also indirectly benefit patients. But the CMS has ruled that these materials—specifically including “medical textbooks or journal reprints”—represent a transfer of value and thus are reportable.

Reporting Costs and Rules

Reporting of reprints is based on the purchase unit cost. For example, if you purchase 10,000 copies of an article for $50,000, the per-unit cost is $5. Although items worth less than $10 don’t need to be reported, manufacturers still need to track that transfer.

Why? Because if the sum of all items for a given recipient exceeds $100 per year, that transfer needs to be reported. So if you were to hand a physician 20 articles with a cost of $5 each—or other transfers of similar value—the total $100 value must be reported.

These rules apply to traditional, “hard-copy” journal reprints, but there are some exceptions that marketers should explore. Notably, CMS has ruled that “small incidental items that are under $10” distributed at conferences or similar events do not need to be reported, or even tracked for “aggregation purposes.”

CMS Guidance

Q: Are items or materials used to educate physicians, which may indirectly benefit patients, included in the education materials exclusion?

A: No, the education material exclusion is limited to materials and items directly benefiting patients or intended for patient use as required by the Affordable Care Act Section 6002.

https://questions.cms.gov/faq.php?id=5005&faqId=8171

CMS Guidance

Q: How should applicable manufacturers or applicable group purchasing organizations determine the value of journal reprints provided to covered recipients?

A: The value of a journal reprint should reflect the cost that an applicable manufacturer or applicable group purchasing organizations paid to acquire the reprint from the publisher or other distributor. Applicable manufacturers and applicable group purchasing organizations may submit an assumptions document clarifying any assumptions made to determine the value of journal reprints.

https://questions.cms.gov/faq.php?id=5005&faqId=8370
ePrint Formats

Physicians, nurses, and other HCPs increasingly access information electronically. ePrint formats simply deliver the identical journal content in digital form. Basically, there are two types of ePrints, with differing implications for Sunshine Act reporting:

- **“View-Only” ePrints** are accessed and read on a tablet or other device. As the name implies, these ePrints can be “viewed only:” they can’t be downloaded, saved, forwarded, or printed. View-Only ePrints involve no physical transaction to the HCP, and thus have no transferable value to be reported.

- **“Downloadable/Printable” ePrints** are electronic versions of articles that can be downloaded in PDF format. As such, they can be printed, stored, or shared with other users. This ePrint format does involve a physical transaction, and thus does need to be reported.

As most readers of this White Paper will know, CMS rules and reporting requirements are open to interpretation. But WKH believes that, consistent with the logic of the rules set out thus far, View-Only ePrint formats can be exempt from reporting.

“I believe that is a fair interpretation because it would be very hard to track and to value a ‘viewed-only’ reprint,” comments John Kamp, Executive Director of the Coalition for Healthcare Communication. “I’d recommend that those wishing to avoid unexpected enforcement pay close attention to the HHS’s evolving policy on the Sunshine rules—especially the Q & A’s posted on the Open Payments website.”

When you purchase WKH ePrints, you also receive valuable use metrics, user authentication, and content control. Each of these ePrint formats has its advantages and disadvantages. We’ll go into more detail when we discuss specific formats below.
Journal Content—Highly Effective, Highly Valued

Today, as always, physicians rate journals as one of the strongest influences on clinical decision-making. In the era of evidence-based medicine and clinical decision support, the impact of peer-reviewed research has never been greater.

Journal content is the original science that substantiates product claims. It’s the basis not only for clinical decision-making but also for pharma marketing. Most claims made in any DTC or other pharma ad originally came from a clinical trial!

Reprints are Strategic

Reprints offer unique strategic value at a time when other options are constrained or disappearing. Marketers sometimes take reprints for granted, just because they’ve always been around. As opportunities for direct contact dwindle, reprints of original research from high-impact published literature are the last thing you have that really explains your drug. In the era of evidence-based medicine, reprints are the evidence!

Even without the Sunshine Act, the shift to digital is transforming the way marketers connect to and communicate with HCPs. As the digital disruption shakes out, journal reprints still let you put that pivotal evidence in front of the right prescriber, at the right time. The only thing that’s changed is the mode of distribution—while reprints were once solely handed out directly from the sales rep’s briefcase, now the same content can also now be distributed in new electronic ways.

“With diminished opportunities for prescriber dialog, advertisers will find reprints even more valuable in the future,” comments Jack Angel, Healthcare Industry Consultant and Board Member of HMP Communications Holdings, LLC. “The WKH strategy of providing access to reprints through avenues such as ad links and subscriber lists simply bridges content distribution to modern-day technology.”

Reprint Solutions for the Sunshine Age

In the remainder of this White Paper, we’ll introduce the range of WKH reprint options. Sunshine Act implications for each particular format are called out using our sunshine symbol.

We’ll also touch on the benefits of each reprint format, including some strategic factors to consider in choosing the most appropriate approach for your product and market.

1. Print Reprints

Hard-copy reprints provide a credible leave-behind with staying power. Physicians can (and do) read them, share them with colleagues, discuss them with patients, and save them for future reference.

- Paper reprints are still a good investment. They are considered a transfer of value and thus are reportable, based on the price per copy. When you purchase reprints from WKH, pricing per unit will be clearly indicated on the proposal and invoice.

If you hand one copy of a reprint to an individual doctor, it won’t necessarily need to be reported. But you should still track that value because aggregate transfers of $100 or more are reportable within the same calendar year. As the Sunshine era is underway, reps need to play a key role in educating HCPs about what’s reportable and under what circumstances.

2. Conference/Event Distribution

Conferences and meetings are a great alternative for reprint distribution. Professionals attending meetings and educational events are “in a learning mode”—they are there to keep up to date and talk to their peers about current practice and new developments. It’s a perfect opportunity to provide them with the scientific evidence behind the latest clinical advances. Of course, conferences are also an ideal venue for eye-catching digital and interactive displays.

- Journal reprints distributed at large-scale conferences are exempt from reporting. The CMS rule on this issue acknowledges that it’s “extremely difficult” to identify individual recipients in large-group settings. The reprint that a doctor picks up at your booth in the exhibit hall doesn’t need to be reported—even if that individual has received other transfers exceeding $100.4

- At conferences or meetings, “View Only” formats displayed on tablet or screen do not need to be reported. See the section on Tablet Detailing for more on effective uses of “View-Only” ePrint licenses.

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3. **ePrint Distribution Via Company or Product Websites**

Manufacturers can post links to WKH ePrints on product websites. This option gives prescribers easy access to key clinical evidence when they’re actively researching treatment alternatives. Deploying ePrints alongside other marketing and educational assets lets you back up claims directly and solidly, using the original science on which they were based.

- “Downloadable/Printable” copies need to be reported. Value based on cost per view.
- “View only” ePrints can’t be downloaded, saved, or printed. Because there is no transfer of value, they may not need to be reported.

4. **ePrint Distribution via Email**

Like reprints used as "leave-behinds" on office visits, email reprints are a great option for follow-up after making initial contact. They reinforce the product benefits, and allow prescribers to spend more time with the data at their convenience.

- “Downloadable/Printable” ePrints emailed to individual physicians are reportable under the Sunshine Act, based on cost per open.

5. **ePrint Embedded into Tablet Detailing**

An essential part of the pharma rep’s sales toolkit, tablet detailing lets you communicate sales messages in compelling, engaging ways. Once reps have the prescriber’s attention, ePrints are another great asset to display alongside other detailing elements—again, showing the original science behind your selling points.

Tablet detailing with ePrints lets you display the most important evidence-based research alongside your eye-catching video, interactive elements, and other assets. Of course, you can follow up with an email or manufacturer-deployed reprint or ePrint, as appropriate.

- ePrints used in tablet detailing presentations are “View Only”—they don’t need to be reported under the Sunshine Act.
6. Reprint Distribution via WKH Advertising and eMedia

WKH offers exciting and exclusive new opportunities for distribution of reprints through various multimedia channels. Leveraging current digital media is a great new way to distribute reprints. Across print, online, and mobile formats, you can provide HCPs with critical content from the journals they know and trust. You can provide specialists with reprints under the aegis of their trusted specialty journal and/or paid journal subscription. Or send primary care providers reprints from specialty journal content they may not have seen before.

By utilizing WKH proprietary distribution channels, marketers can now deploy their clinical message to HCPs while still avoiding reporting requirements. CMS guidance on third-party distribution states that the transfer is exempt from reporting as long as the manufacture is unaware of the identity of the covered recipient.

WKH Advertising and eMedia can help you enhance your marketing and advertising to create a meaningful product experience within the trusted learning environment of our prestigious journals. Below are just some of the new opportunities for distributing journal reprints:

- **WKH Print & App Bundle**
  - Embed an ePrint link into the digital version of your journal advertisement.
  - **Case Study:** One recent advertiser saw a 100% increase in Engagement (taps) after adding an ePrint link to its journal app.5

- **WKH Banner Advertising**
  - Embed ePrints into your website banner ads. Providing dynamic, expandable rich media engages journal visitors in your content without taking them away from the website they’re visiting.
  - Add a “Call to Action” link on your product website to drive higher opens of your ePrint.

- **WKH Homepage Text Link Sponsorship**
  - Promote up to three ePrint links on the journal website homepage, driving visitors to your ePrint hosted on your product website.

- **WKH Article Connection**
  - Make your website sticky with an RSS feed delivering “High-Impact” articles from WKH journals directly to your product website or portal.

- **WKH Print Distribution**
  - Distribute hard-copy reprints polybagged with subscriber copies.

**WKH Direct Access Email**

Advertisers can also distribute ePrints via WKH’s “opt-in” database. Our lists include 1.2 million names, broken out into 20 different clinical areas. All are verified subscribers who have expressed an interest in receiving content from WKH, a trusted publisher known for its high-quality clinical content.

- With a 18% open rate and 9% average click-through rate, Direct Access Email is a high-impact option for reaching clinicians.5
- Pairing an ePrint with other product information provides immediate access to definitive evidence on product benefits—delivered straight to the recipient’s inbox.
- WKH Direct Access Email recipients are covered by WKH’s privacy policy. Their names are not reported to list purchasers.
Bring Your Own Ideas!

Marketers are coming up with ever-more innovative and creative ways of engaging potential customers using compelling digital and online presentations. Almost any idea you come up with can be enhanced with the addition of key journal content!

“The best approach to is to work with our trained group of solution specialists to develop a program tailored for your marketing objectives,” says Fabien Savenay, Vice President of Advertising Sales, Wolters Kluwer Health - Medical Research.

Showcase the Evidence Behind Your Product

With tight budgets, new media, and now the Sunshine Act, marketers need to find creative ways of presenting clinicians with critical evidence of product effectiveness. Reprints of journal content are a uniquely valuable tool to help you meet this challenge. Reprints give prescribers access to definitive evidence from their preferred source of information for clinical decision-making: authoritative, published, peer-reviewed research journal content.

WKH provides a wide range of options for distributing and driving views of reprints in practically every area of practice, from Anesthesiology to Trauma, and everything in between. You can draw attention and readers to YOUR research evidence that provides your product’s benefits to clinicians while they are reading current journals digitally or in print, attending conferences, doing online research, and even checking email.

WKH delivers not just the article but also a distribution model that gets the right article to the right physician at the right time. WKH gives you options and information to help you manage Sunshine Act reporting requirements. While you should always consult your company’s compliance policies, WKH reprint solutions keep you “on the sunny side” of the Sunshine Act while helping you put critical evidence in the hands of the right prescriber.

Representatives are available for appointments to demonstrate our capabilities and discuss how they can enrich your marketing and advertising strategy.

Contact us today by visiting www.wkadcenter.com or email us at wkadcenter@wolterskluwer.com.

Additional Resources

- Coalition for Healthcare Communication: http://www.cohealthcom.org/