



# Rx For The Defense

The newsletter of the  
Drug and Medical Device Committee

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## Committee Leadership



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## Leadership Notes

## Chair's Corner

By Sara J. Gourley



Happy summer! It was great to see so many of you at our seminar in New York City in May. Our presenters were terrific, and addressed topics ranging from MDLs to cyber-risks, to practical tips on trial practice. Our Marketing Committee, chaired by Sherry Knutson of Tucker Ellis and Archie Reeves of McDowell Knight Roedder, did a great job promoting the seminar, and we had almost 600 people attend. Dine-arounds were a new addition this year and many signed up to connect with colleagues at some of New York's great restaurants. Erik Snapp organized a DRI For Life run/walk around Central Park for our DRI-athletes of all levels! Kim Beck of Ulmer & Berne led the effort to secure a number of counsel meetings, which allowed our members to attend a great seminar and also connect with their clients. Thanks to the companies which hosted counsel meetings as well as the sponsors of our seminar. As usual, a number of law firms sponsored after-hours receptions for attendees, which provided yet another networking opportunity. After our seminar adjourned on Friday, a hearty group of drug and device lawyers led by Jim Craven of Wiggin & Dana sorted clothing donations at the Covenant House in New York. Covenant House serves homeless youth in New York, and in other cities. Thanks to generous

donations made by our seminar attendees, our team also delivered \$1,000 to The Covenant House. We are proud to support the efforts of those who make our communities a better and more welcoming place.

I hope you are planning to join DMD leadership at DRI's Annual Meeting in San Francisco on October 17-21, 2018. In addition to many fine main stage programs and exciting networking opportunities, our Committee will sponsor a special presentation Friday on Current Trends and Hot Topics Emerging in Products Liability MDLs and State Coordinated Litigation, followed by a Committee meeting. Many thanks to our Committee's Annual Meeting Chair, Kelly Jones Howell of Harris Beach, for putting the program together.

I hope you have a wonderful summer! See you in San Francisco in October.

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## From the Editors

By Kimberly Beck and Heather Howard



Now that the DRI Drug and Device Seminar is over, it must officially be summer! If your summer reading list includes any interesting recent decisions, or if you've had too much time outside in the sunshine and would rather sit in the shade and write an article, look no further than *Rx for the Defense*. We have several authors lined up for our upcoming editions of *RX for the Defense*, but we are still looking for more, and we also always welcome articles about cutting edge issues or major new court decisions. If you would like to submit an article for publication, please

contact Kim Beck at [kbeck@ulmer.com](mailto:kbeck@ulmer.com) and [Heather Howard at howard@kslaw.com](mailto:howard@kslaw.com).

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## Feature Articles

### Who's on the Hook?

# The Product Liability Implications of 3D Printing and Patient-Matched Devices

By Brett A. Tarver and Amber D. Greenaway



Despite the revolutionary ability of 3D printing of medical devices, uncertainty remains about the legal implications of products liability that 3D printing presents. This article discusses the legal challenges with regard to potential tort liability for defects in patient-matched devices (PMDs). This article also reviews the FDA's recent guidance on 3D printing and its effect on the current regulatory landscape.

3D printing is an additive manufacturing process that creates a physical object from a digital design. 3D printed medical devices can come in many forms. In one form, a device can be printed from a standard design from a 3D printer that has the capability to print multiple identical copies of the same device. Another form of devices, called PMDs, are printed by 3D printers that have the design capabilities to create a device that is specific to a patient's individual features because the device is designed from a patient's own medical images rather than a standard digital file. The printer allows for a healthcare provider, like a physician, to input patient-specific parameters prior to the printing of the PMD. The FDA regulates 3D printed medical devices through the same pathways as traditional medical devices. However, the advent of 3D printing of PMDs has given rise to two important legal questions. First, the relevant "product" must be determined. Second, who will be considered the device manufacturer must also be determined. The answer to these two questions may have both regulatory and liability implications. In the absence of cases, defense counsel should keep an eye on developments in the areas discussed below in order to develop strategies for reducing potential liability exposure.

The first challenge that 3D printing of PMDs presents is that the PMDs fit awkwardly into the traditional definition of "product." The number of possible "products" could

range from the 3D printed PMD to the 3D printer itself to the digital scans of the patient to the software designs that are customized for the patient. The Restatement (Third) of Torts defines a product as "tangible personal property distributed commercially for use or consumption." Restatement (Third) of Torts: Prods. Liab. §19 (Am. Law Inst. 2015). At first blush, it appears that this definition could exclude any electronic designs or digital scans due to their intangibility. However, the Ninth Circuit suggested in dictum that computer software might be considered an intangible product for purposes of strict products liability. *Winter v. G.P. Putnam's Sons*, 938 F.2d 1033, 1036 (9th Cir. 1991); see also *Corley v. Stryker Orthopaedics*, No. 13-2571, 2014 WL 3125990 (W.D. La. July 3, 2014) (determining that the plaintiff's allegations of defective software survived a motion to dismiss because the software was a necessary part of the customized medical device and thus subject to products liability laws). Another possibility is that the courts may draw an analogy between the treatment of software under the Uniform Commercial Code and under products liability law. Restatement (Third) of Torts: Prods. Liab. §19, reporters' note to cmt. d, at 278-79 (Am. Law Inst. 1998). Under the Code, software that is mass-marketed is considered a good whereas software that is developed specifically for the customer is a service. *Id.* Whether the 3D printer itself is considered the "product"—as opposed to the PMD which is implanted in the patient—must also be distinguished.

Second, another challenge is determining who the appropriate manufacturer is. The determination of what the relevant "product" is will affect the determination of who the manufacturer is for both regulatory and liability purposes. If the digital software and designs are not considered products, then injured parties cannot pursue liability

claims against the software developer because products liability law requires proof of a defect with respect to a “product.” If the finished PMD is considered the product then another issue arises: is the appropriate manufacturer the doctor who inputs the patient-specific data into the 3D-printer or is it the party who created the 3D printer itself? The Restatement states that courts often decline to impose strict liability on defendants whose primary objective is providing services. Restatement (Third) of Torts: Prods. Liab. §19(b) (Am. Law Inst. 1998). Thus, doctors and hospitals, which have traditionally been characterized as service providers, are unlikely to be deemed manufacturers if the 3D printing occurs off-site and is later shipped to the prescribing healthcare provider. However, issues arise when 3D printing occurs on-site because this point-of-care manufacturing disrupts the traditional “manufacturer”-based chain-of-sale concept on which liability is often based. Because both the medical images and the PMD are created on-site, it is unclear whether healthcare providers and suppliers would be considered “manufacturers” of these PMDs and thus subject to regulatory controls and product liability laws.

In 2017, the FDA released initial guidance regarding 3D printing and provided insight into how the aforementioned challenges might be resolved. The guidance states that “patient-matched device designs may be modified either directly by *clinical staff*, *the device manufacturer*, or a third party in response to clinical inputs.” Food & Drug Admin., Technical Considerations for Additive Manufactured Devices: Guidance for Industry and Food & Drug Administration Staff [ ](2017) (emphasis added). The listing of both “clinical staff” and “device manufacturer” may suggest that the FDA will retain the traditional characterization of doctors and hospitals as service providers. However, FDA Commissioner Scott Gottlieb stated that the FDA is “working to establish a regulatory framework for how . . . to apply existing laws and regulations that govern device manufacturing to *non-traditional manufacturers like medical facilities* . . . that create 3D-printed personalized devices for specific patients that they are treating.” Statement by FDA Comm’r Scott Gottlieb, M.D., on FDA Ushering in New era of 3D Printing of medical products; provides guidance to manufacturers of [medical devices](#) (Dec. 4, 2017) (emphasis added). Gottlieb went on to explain that the FDA plans to explore the “role of *nontraditional manufacturing facilities like a hospital operating room*.” *Id.* (emphasis

added). Thus, it is unclear how the FDA will resolve the aforementioned legal questions.

In conclusion, the advent of 3D printing has presented issues regarding the relevant product and appropriate manufacturer. The crux of potential products liability turns on what the “product” is. Once the relevant product is designated, it largely answers the question of who the appropriate manufacturer is. Although the guidance contains nuanced implications, the FDA may soon declare what the relevant product is and whether onsite 3D printing of PMDs constitutes “manufacturing” which requires compliance with the FDA’s regulations governing such entities. Until then, defense counsel should be aware of the inadequacies and uncertainties in the law, so that they can protect their drug and medical device manufacturer clients from liability going forward. Counsel should attempt to reduce potential liability exposure by developing strategies to produce greater traceability of designs and raw materials, including obtaining the appropriate levels of professional indemnity coverage with insurers. Counsel should also remember that if digital software and designs are deemed products, then presumably its manufacturer would have to include with those digital files the same product warnings that accompany the physical device. Moreover, counsel should ensure that entities who design software for or build 3D printers clearly identify relevant design parameters, pre-determined ranges for these parameters, and which of these parameters can be modified for patient matching.

[The views and opinions set forth herein are the personal views or opinions of the author and co-author; they do not necessarily reflect views or opinions of the law firm with which they are associated.](#)

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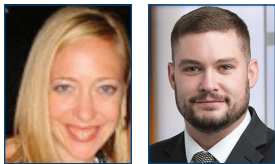
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## An Introduction for Newer Lawyers

# Mediating Medical Device Claims

By Jennifer Haccoun Abramson and Thomas Pack



### Overview: Mediation Is the New Trial

Only three percent of civil tort, contract, and real property cases go to trial in state courts in the United States. See U.S. Dep't of Justice, [Bureau of Justice Statistics, Civil Bench and Jury Trials in State Courts](#), 2005 (Apr. 9, 2009). Similarly, all federal courts are required by statute to implement alternative dispute resolution (ADR) procedures, including mediation. 28 U.S.C. §651. ADR programs, including mandatory mediation programs, are also common in state courts and provincial courts in Canada. See, e.g., Minn. Stat. §484.76, Ont. R. Civ. P. 24.1.

What's the point? A litigator may still be judged by her jury trial win record, but mediation skills are *far* more likely to be exercised in day-to-day litigation practice. Given the increasing dearth of jury trials, and the prevalence of ADR programs, a litigator's first and only chance to present the merits of his case for neutral assessment may well be mediation.

But mediation requires different skills and a different mindset than other phases of litigation, and these skills are often at odds with a young litigator's training. Mediation is not about "winning" or achieving the "right result," which you likely believe would be a full defense verdict or summary judgment order. For large corporate clients, resolving a matter through mediation is about making strategic business choices which allow for financial certainty. Your client may choose to settle even if the plaintiff is sure to lose any given case, or the client may vigorously oppose a small-dollar claim to discourage plaintiffs with nuisance claims from suing in the first place. The business choice is your client's to make! For the young lawyer, mediation requires a shift in thinking. You are your client's *business partner*, and you must zealously advocate for your client's *business interests*. Often, this will involve securing a favorable (and certain) settlement, which is often more than you think the plaintiff is entitled to, but which gives your client peace of mind.

### Before Mediation: Mediator Selection

Much of the work of mediation will occur before mediation, particularly on the defense side of a drug/medical device products liability case.

The parties will generally be asked to agree to selection of a mediator, though various courts have provisions for judge-led mediation. See, e.g., Civ. L. R. 9, Santa Clara Cnty. Sup. Ct. (Cal.); Que. Code Civ. Proc., art. 151.15. Your client may know mediators who have successfully mediated cases with their products in the past, and there is an advantage (for both sides) to having a mediator who is familiar with drug and medical device litigation and the products at issue. There are various factors that may affect your choice of mediator, and it sometimes just comes down to a preferred style or a prior relationship. But one often-overlooked factor is the disparity in emotional responses between the different sides of the "v." For example, your client is a business, and may well be a large business with a substantial in-house law department. Emotions are not likely to weigh heavily in your client's settlement position, or to substantially affect the way your client makes and/or responds to settlement offers. The entire point of settlement is to achieve a reasonable compromise given the risk factors in any given case in view of the ultimate wildcard—a jury of lay citizens.

But the drug and medical device plaintiff is in an entirely different position. The plaintiff has often suffered some traumatic injury, has required additional medical interventions or surgeries, or is a surviving family member after a death. While you assert that your client had no role in the incident, the plaintiff views you as the representative of the company which caused their injuries. In short, plaintiffs are more likely to be influenced by emotions, which you should keep in mind when you select a mediator. Make sure your mediator can show sympathy for a client's injuries. Consider a mediator with plaintiff-side experience, who the plaintiff will see as fair and credible, and yet can inform the plaintiff that his case has serious problems and encourage settlement. You may assert a complicated defense (from a lay perspective), like preemption or the learned intermediary doctrine, and you want a mediator who can explain the issues to a plaintiff and perhaps even commiserate about the perceived "unfairness" of the law on these points. The

ability to emotionally connect and sympathize with the plaintiff—a characteristic you may not care about in a judge or arbitrator—may be *exactly* what you need to encourage a plaintiff to settle with the “big bad corporation” she has sued.

## Before Mediation: Timing of Mediation and Client Preparation

The optimal timing for mediation depends on a variety of factors, including the relationship between counsel, the level of fact-intensiveness of any given case, and the real-world settlement value of the claims. It is efficient to have an early mediation to avoid substantial litigation expense, unless the mediation is so early that the parties lack key factual information regarding the alleged defect, medical causation, or damages, which may make the mediation session an expensive fool’s errand.

Even so, the parties do not have to wait until the close of fact and expert discovery to have an effective mediation. Courts are often willing to stay cases to allow for mediation. (Anything to encourage settlement!) Internal documents can be produced pursuant to a confidentiality agreement, and medical and other records can be obtained via a release from the plaintiff. If the parties have a good working relationship, this can be cheaper and more efficient than formal discovery. If they do not, then it may make sense to wait until key documents have been exchanged and key depositions have been taken. You may also want to consult experts to ensure you understand the engineering or medical science issues in the case, though be sure to understand what expert communications are and are not subject to discovery in your jurisdiction. See, e.g., *Nat’l Steel Prod. Co. v. Superior Court*, 164 Cal. App. 3d 476, 485 (Cal. Ct. App. 1985) (work product “privilege is waived with respect to all communications to that expert” that was designated as a testifying expert for trial).

You should also volunteer to prepare an objective, comprehensive mediation memorandum for your in-house client. The level of comprehensiveness will depend on your client, but at any rate, there needs to be *no surprises* for your client at mediation—at least that could have been avoided by preparation in advance. If your in-house contact is on the business side, and lacks a legal background, you will need to be even more thorough in explaining the potential downsides of going to summary judgment or trial. If, on the other hand, your client is a seasoned in-house attorney who has mediated far more times than you have, your memorandum may be direct and case-specific, depending on your client’s preference.

Even your seasoned in-house attorney client may still ask you to help support the business case for settlement authority by providing information regarding your experience with similar plaintiffs or the same plaintiff’s counsel. The client may also request a realistic—and not overly optimistic—assessment of the strengths and weaknesses of the case, written for a business audience. It is also worth the time to think of any tricks you can foresee the plaintiff using to drive up the cost of litigation for your client. Your client needs to understand all “good” and “bad” facts you are aware of or can foresee, as well as the pitfalls inherent in any given jurisdiction, especially if it is a so-called “judicial hellhole.” See, e.g., Cal. Code Civ. Proc. §2025.250(d) (a plaintiff can compel a nonresident corporate deposition—on *all designated topics*—to take place physically anywhere within the California county where the action is pending, no matter where the most qualified deponent is).

If your in-house client believes the case should be settled, all of this information can help convince the business side to provide the settlement authority needed to get a deal done. It can also help your in-house attorney client mitigate overconfidence bias, which in litigation is the tendency for a client to overestimate the chances of success, with his or her business clients, and clearly express the factors that mitigate in favor of settlement in any given case.

## Before Mediation: Preparing the Mediation Statement

With key facts in hand and explained to your client, most mediators require a confidential mediation statement, which takes the form of a letter or memorandum to the mediator. This statement provides an overview of the case and lays out your client’s position. Sometimes a mediator will also require a non-confidential mediation statement, or a mediation brief to be shared with the other side.

Remember: in either case, the burden to educate the mediator and facilitate a productive mediation can fall disproportionately on *you* as defense counsel. This is all the more true if your opponent has a high-volume business model. The plaintiff may have done little to prepare her case, and may be simply unaware of damning facts in medical records and other documents. While you may be tempted to delay thorough review of documents until it is time to prepare for a treating provider or plaintiff deposition, the presence of those documents at mediation can push down the settlement value of a plaintiff’s case.

The content and tone of the mediation statement will differ with each case. But in all cases, the mediation statement provides an invaluable opportunity for you to lay out the merits of your case—usually for the first time—to a neutral third party. Though each mediation statement will vary, here are some questions to consider:

- If this is a medical device case, how much background is going to be necessary to fully educate the mediator regarding the science and function of the device?
- Will you need to include a substantial amount of background regarding the underlying disease, surgery, or injury leading to the need for the device?
- What are the *key* documents that can be attached to the mediation statement? A mediation statement should not resemble a motion for summary judgment, but key documents can provide context and can provide the mediator with easy talking points to the other side. Remember that these documents do not need to be admissible—so consider creating a highlights page, summary, or excerpting long documents.
- What expert opinions do you need to have *in advance* of the mediation statement to be included therein?
- Is there information regarding past negotiations, personal difficulties between counsel or the parties, or any other information that should be shared with the mediator in a confidential submission, or even a phone call?

Preparation of a mediation statement is a lot of work, but preparation of an effective mediation statement can make mediation the last day of your case—and can make for a happy client. If the case does not settle, the thought and work you put into your mediation statement often is helpful at framing your case for dispositive motion practice later.

### At Mediation: Effective Advocacy

It is impossible to predict how your mediation will go—though anecdotally, be prepared for most of the action to occur near the end of the mediation session—but there are some things to prepare for.

You should discuss with the mediator or his staff in advance how the mediation will occur. Will there be a joint opening session, at which you or your client should be prepared to give an opening statement? Or will the mediation proceed directly to shuttle mediation, where the mediator shuttles between the parties in separate conference rooms? Should the parties start with a half-day session, or a single day instead of two, with the understanding that

the parties will stay longer if all agree that the mediation is progressing toward settlement?

If you or your client are expected to speak, think about the tone of your opening statement. You will always want to be genuine, and acknowledge the plaintiff's injury or loss even though you disagree with them on many topics. Be prepared to hear an emotional response from them, but you have to trust that the mediator can get them back on track, if you have selected the proper mediator as indicated above.

Remember, once you are in the main mediation session, everything is confidential. With your client's buy-in, consider showing your cards to the mediator. Obviously you do not need to disclose damaging facts that have not come out in discovery because the plaintiff has failed to properly seek them, but that is the rare case. Most cases settle, and most medical device products cases involve the same *basic* issues of defect, causation, damages, preemption, and the like, so you can tip your hand a bit with the mediator.

Finally, prepare for contingencies. If plaintiff mischaracterizes a document, have access (at least electronically) to review and respond. If the case warrants it, consider asking your experts and technical client contacts to be available for calls to discuss novel theories that are unveiled at mediation. You may want to plan a very late flight or plan to stay the night, so mediation is not cut off prematurely by travel plans. Though you cannot prepare for every eventuality, it makes sense to try.

### After Mediation: Prepare for Further Negotiation/Mediator's Proposal

The mediation has ended without a settlement. You are tired, perhaps a little cranky, and may have a flight to catch. What next? Your mind is likely on the mountain of discovery awaiting you, teeing up a motion for summary judgment, and trial preparation.

Do not become too discouraged. With a good mediator, the mediation process is not over yet. If the mediator believes a settlement can be achieved, she will stay involved and help the parties continue to negotiate. Perhaps another day of mediation is what the parties need to seal the deal. Or it may be that one critical deposition can fill the factual void, uncovered at mediation, that kept the parties from reaching an agreement. Or the mediator may suggest preparation of a "mediator's proposal." If you trust the mediator, and believe the parties all have a good rapport with her, then this is often worth pursuing.

A mediator's proposal is a proposed set of settlement terms the mediator believes could be accepted by both parties. The settlement figure (and associated terms) is provided to the parties as a take-it-or-leave-it offer, and the parties respond to either accept the offer or decline the offer. If both parties accept the offer, a settlement is announced. If one or both of the parties decline the offer, the results stay confidential. This is important because a mediator's proposal may represent a significant change in position for the accepting party, which could be used against it in future negotiations.

Mediators' proposals are effective in a surprising number of cases, perhaps because the parties perceive the neutral mediator's evaluation as a fair valuation of the case. While your client is likely experienced in litigation, and is adept at valuation of cases, this perceived fairness can be a particularly effective way of making the plaintiff move to a reasonable position. And though settlement of a winnable defense case can be a hard pill to swallow, remember: there's value to settlement, and your client is likely to prefer certainty over the prospect of a large judgment and equally large bills from your law firm for trial.

This manuscript was prepared for the authors' presentation at the Young Lawyers Blockbuster during the 2018 Drug

& Medical Device Seminar, entitled "Mediation is the New Trial: Partnering with Clients for Success."

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## The Perfect Storm

# Final Warnings from the Feds About Liability MSAs

By John V. Cattie, Jr.



The *Andrea Gail* never had a chance. The Gloucester, Massachusetts, fishing boat was old and rickety. Its grizzled crew was experienced but vastly overmatched. And the storm it faced was simply perfect.

One fateful decision doomed the *Andrea Gail*. Instead of heeding warnings about the powerful storm, it ignored all warnings and tried to push through the storm unprepared. Getting home before its cargo of swordfish spoiled was more important than protecting themselves.

The third-party liability insurance settlement community stares today at its Perfect Storm. The combination of rapidly rising Medicare enrollment rates, a longer American life expectancy and the pending repeal/replacement of the Patient Protection and Affordable Care Act (ACA aka Obamacare) leaves government officials seeking

alternate means to maintain the solvency of the Medicare Trust Funds.

Meanwhile, the Medicare Secondary Payer (MSP) Act sits by, ready and waiting. While Medicare has considered active enforcement of the MSP Act's future medical provisions previously for liability insurance settlements, no final indication has been given to that occurring until now. Late in 2017, Medicare began rejecting certain repayment requests from medical providers, advising providers to seek repayment from the patient's Liability Medicare Set-aside Arrangement (LMSA).

The Perfect Storm is set to hit third-party liability insurance settlements. Parties settling these cases need to heed the warnings and be prepared. Addressing LMSA exposure on all cases involving future medicals is now your best chance to ride out the storm.



## The Storm Brewing: How We Got Here

After World War II, birth rates in the United States skyrocketed. The resulting Baby Boomer generation came of age in the 1970s. Understanding the potential strain this generation may later place on a Medicare program in its infancy, Congress passed, and President Carter signed into law the MSP Act on December 5, 1980.

The MSP Act provides a broad prohibition on Medicare paying certain medical expenses. Medicare will not pay for a beneficiary's medical expenses where payment has been made under a liability insurance plan (including self-insurance). 42 U.S.C. §1395y(b)(2)(A)(ii). To the extent that a liability insurance carrier or a self-insured pays a claimant for future medical expenses related to the settlement, the federal government (and the American taxpayer) will not pay those future bills but for one exception.

Conditional payments represent the only exception to this broad statutory prohibition. Medicare may make a conditional payment on behalf of its beneficiary when an entity has not yet accepted responsibility to make payment. 42 U.S.C. §1395y(b)(2)(B)(ii). Medicare pays on the condition that it will be reimbursed when an entity accepts responsibility for that payment and that responsibility is evidenced in a judgment, a compromise for release or other means. Id.

For years, most stakeholders in the liability insurance settlement community ignored these MSP future medical statutory provisions. Settling parties rarely addressed them and Medicare never said one word about them. Only after the Centers for Medicare & Medicaid Services (CMS) provided guidance about future medicals for the workers' compensation community did parties in the liability insurance community begin asking questions.

Slowly, CMS began to address the LMSA issue publicly. In 2011, CMS released its only LMSA policy memorandum addressing use of a treating physician's letter to conclude that no LMSA was needed. In 2012, CMS released an Advanced Notice of Proposed Rulemaking (ANPRM) about LMSAs. In 2013, CMS issued a Notice of Proposed Rulemaking (NPRM), though that was never released publicly. In 2014, CMS voluntarily withdrew the NPRM.

Many lobbying groups took the opportunity to congratulate each other when CMS withdrew the NPRM. "Mission Accomplished," they said. The LMSA issue was dead according to them. It leads one to wonder how they missed the storm brewing on the horizon.

## The Weather Map: Why Now?

Three primary factors are driving the LMSA issue in 2018: 1) rapidly rising Medicare enrollment rates short term; 2) longer life expectancies; and 3) the repeal/replacement of the ACA. This combination will rapidly deplete the Medicare Trust Funds over the next ten (10) years. Something must be done to preserve the integrity of the Medicare program, and CMS knows that.

News about rising Medicare enrollment rates cannot be considered "Breaking News." For years, government officials have tracked how Baby Boomers age and at what point they enroll in Medicare. Until recently, Medicare enrollment for Baby Boomers happened not due to age, but after receiving Social Security Disability Income (SSDI) benefits, having End Stage Renal Disease (ESRD) or being afflicted with amyotrophic laterals sclerosis (ALS aka Lou Gehrig's Disease). Now, Baby Boomers are aging into Medicare enrollment status, driving enrollment rates higher.

The statistics are striking. When the MSP Act was signed into law, just over 28 million Americans were Medicare enrolled. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareEnrpts/Downloads/SMI2013.pdf> (last visited June 1, 2018). That number grew to 41 million over the next 25 years. Around 2005, the numbers began to rise more rapidly. As of 2015, approximately 55 million Americans were Medicare enrolled. Officials predict that figure will exceed 80 million by 2030. <https://kaiserfamilyfoundation.files.wordpress.com/2013/06/projected-change-in-enrollment-2000-2050-medicare.png> (last visited June 1, 2018).

Every one of those individuals will need healthcare coverage, whether related to a liability insurance settlement or otherwise. You may not be one of those individuals today. If not, chances are good you will be within 25 years. Funds deposited to the Medicare Trust Funds going forward need to exceed funds withdrawn from the Medicare Trust Funds to ensure the long-term solvency of the Medicare program.

Longer life expectancies exacerbate this problem. Americans live longer lives in 2017 than they have historically. American life expectancies have increased 5.1 years from 1980 to 2017, despite a recent downtick due to our country's opioid epidemic. <https://www.cdc.gov/nchs/fastats/life-expectancy.htm> (last visited June 1, 2018). That translates into a larger elderly population using Medicare as the primary insurance provider. The elderly visit the doctor more, need more medical procedures and take more prescription medications. Living longer is good news, but

only if the elderly have Medicare to pay for healthcare in their 70s, 80s and beyond.

The third ingredient to the Perfect Storm is the anticipated repeal and replacement of the ACA. The ACA extended the life of the Medicare program. By moving more uninsured individuals to private health plans, less strain was placed on Medicare. According to Medicare, studies show that the ACA contributed to the life of the Medicare Trust Funds being extended by approximately 12 years. <https://www.medicare.gov/about-us/affordable-care-act/affordable-care-act.html> (last visited June 1, 2018).

The November 2016 general election rocked the health-care landscape. With Republicans now in control of the White House and both chambers of Congress, repealing/replacing the ACA became job #1. While full repeal now appears off the table, the current administration is taking steps to tear down the ACA piecemeal. The Medicare Trust Funds are directly and negatively affected by these factors.

## Today's Forecast: CMS Moves to Announce LMSAs

In 2018, we have more people in the Medicare system living longer lives and incurring more medical expenses. At the same time, we are removing a tool that had extended the life of the Medicare Trust Funds. Understanding these volatile atmospheric conditions, CMS officials have no choice but to act.

They know that it has future medical provisions of the MSP Act, which have been in effect for 37 years sitting on the shelf. They know the law already exists for CMS to deny payment appropriately where payment has already been made under a liability insurance plan. 42 U.S.C. §1395y(b)(2)(A)(ii). They know that responsibility is evidenced by a primary plan or payer as part of a settlement of a liability insurance claim. 42 U.S.C. §1395y(b)(2)(B)(ii). They know that responsibility is transferred from defendant/insurer to the claimant as part of settling the case. [https://www.cms.gov/Medicare/Coordination-of-Benefits-and-Recovery/Workers-Compensation-Medicare-Set-Aside-Arrangements/Downloads/WCMSA-Reference-Guide-Version-2\\_7.pdf](https://www.cms.gov/Medicare/Coordination-of-Benefits-and-Recovery/Workers-Compensation-Medicare-Set-Aside-Arrangements/Downloads/WCMSA-Reference-Guide-Version-2_7.pdf) (last visited June 1, 2018). They know that the plaintiff is then responsible for future medical expenses related to the compensable claim going forward as the primary payer under the terms of most settlement agreements. They know its right of recovery is not linked to the actual establishment of an LMSA, but rather when CMS is presented a bill prematurely, which CMS then pays in error. CMS officials

understand all this. They also understand the high level of non-compliance and complete ignorance settling parties in the liability insurance settlement community have had on this issue for decades now.

Knowing that the liability insurance settlement community would need time to prepare, CMS has issued several warnings recently. On June 8, 2016, CMS announced that it was considering expanding its formal MSA review process to include LMSAs. The announcement fell mainly on deaf ears.

Late in 2016, CMS released a Request for Proposal (RFP) to find a new Workers' Compensation Medicare Set-aside Arrangement (WCMSA) review contractor. Contained in the RFP was work flow for LMSA review. At CMS' discretion, it would ask the new WCMSA review contractor to review upwards of 51,000 LMSAs per year in addition to the 19,700 WCMSAs it anticipates reviewing annually. While CMS did not announce this formally, it was information made available to the public when it solicited bids for the new WCMSA review contractor.

Now, CMS has told the medical community about LMSAs. In an article dated November 8, 2017, SE17019 provides the medical community direction about how to accept payment from a patient's LMSA. <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Net-work-MLN/MLNMattersArticles/downloads/SE17019.pdf> (last visited June 1, 2018). By providing this direction to medical providers, CMS has closed the loop, providing us one last warning about the Perfect Storm on the horizon.

## Will the Storm Break: What About Enforcement?

Storms sometime dissipate. A Category 5 hurricane in the middle of the Caribbean may only make landfall in the US as a tropical depression. Maybe things won't be as bad as it appears. So, while CMS makes these moves and gives us warnings to prepare, you may be asking, "How can CMS enforce this? What gives it the right?"

From the statutory perspective, CMS already has enforcement tools in hand. It's true that the MSP Act does not require MSAs of any kind (WC, liability or otherwise). The MSP Act, however, does clearly provide rights of repayment when another entity has responsibility to pay that same item, service or expense. 42 U.S.C. §1395y(b)(2)(A)(ii).

The MSP Act also provides CMS with stiffer enforcement penalties. CMS has the statutory right to collect not only the amount of the overpayment made in error, but the

right to collect twice that amount or double damages. 42 U.S.C. §1395y(b)(2)(B)(iii). The United States also has subrogation rights under the MSP Act. 42 U.S.C. §1395y(b)(2)(B)(iv).

Even more potent, CMS also has the option to tap the federal False Claims Act. 31 U.S.C. §§3729, *et seq.* If CMS believes actors are committing fraud against the Medicare program by billing Medicare for services rendered instead of paying for those out of settlement proceeds received for that specific purpose, the potential penalties are steep. Fines between \$10,781 and \$21,563 per occurrence plus three times (3x) the amount of financial harm caused to the Medicare program can be levied by the U.S. Department of Justice (DOJ). 31 U.S.C. §§3729(a).

These various penalty provisions provide the devastating force behind any enforcement in this area. *Nothing else* needs to develop or be enacted for these penalty provisions to be used. Enforcement tools are in place, and ready for CMS and/or the DOJ to use immediately if desired. No notice or warning from CMS about choosing to use the penalty provisions is needed.

“But how will Medicare find out about the LMSA?” A reasonable question to ask today though one that sounds in policing and enforcement as opposed to understanding and following the current law. No formal review process currently exists for LMSAs today. Expect that to change later this year when CMS exercises its option to have its new WCMSA review contractor also review LMSAs.

Also expect CMS to add new data points to the MMSEA Section 111 report. Those new data points could ask if an LMSA was funded and if so, for how much. When CMS does this, every liability insurance carrier or self-insured in the U.S. will need to change the way they report to Medicare to take this issue into account. A change in reporting will lead to changes in how the issue is addressed. Simply put, too much is at stake for CMS to wait any longer, especially when the fix can be so simple to implement.

## Conclusion

The liability insurance settlement community has received plenty of warning about the Perfect Storm. Nothing needs to be changed in the law or the regulations for CMS to deny payments for future medical expenses. Nothing needs to be changed in the law or the regulations for CMS to pursue repayment of future medicals from primary plans and payers.

Some, though, will continue to ignore the warnings. Whether it is ego, ignorance or incompetence, their fate is sure to be the same as the *Andrea Gail*. The crew of the *Andrea Gail* faced a fateful decision. Push through the storm or seek shelter and safe harbor? The *Andrea Gail* took a risk, pushed forward unprepared and lost everything.

The time for your clients' fateful decision is at hand. It's time to heed the multiple storm warnings. You should seek shelter and safe harbor. You should take the time to become informed on LMSA issues and how they may affect your case. Preparing for a storm costs little; cleaning up from the storm could cost much more.

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