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# Colorado Health Law Symposium

*Co-sponsored by the Health Law Section of the Colorado Bar  
Association*

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# Colorado Health Law Symposium

## April 15, 22, & 29, 2021

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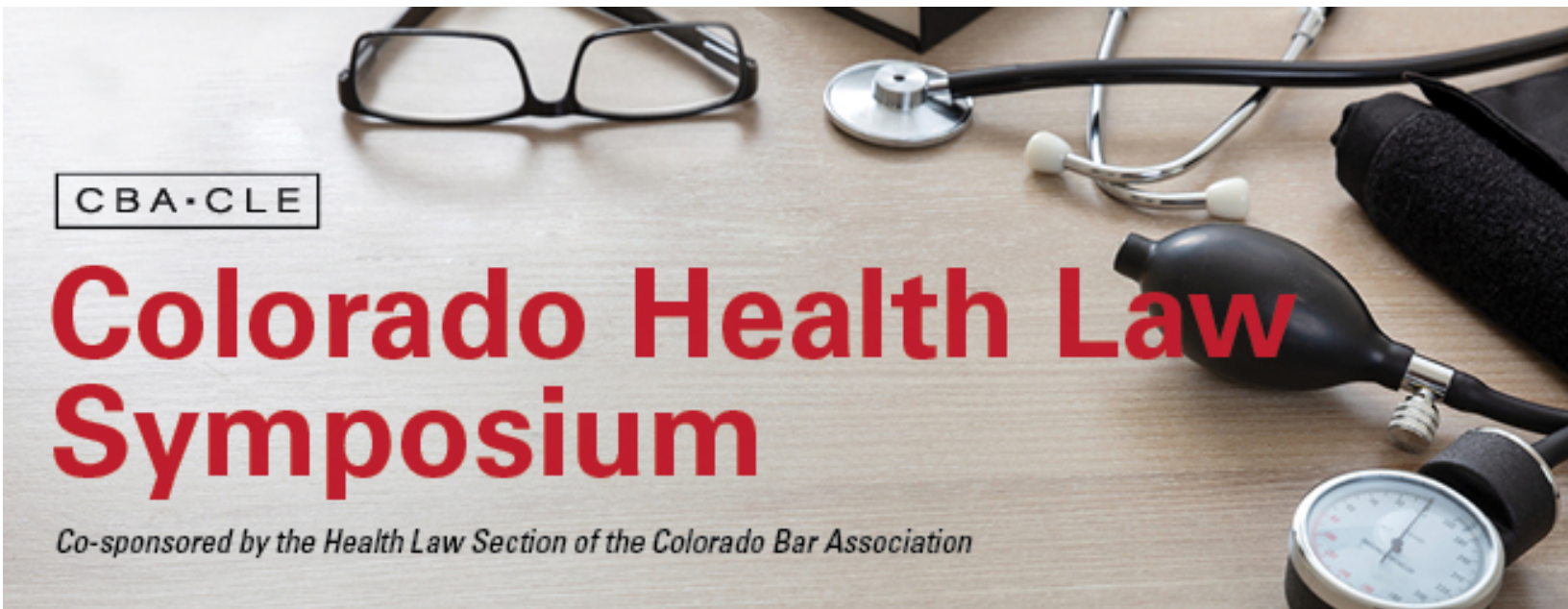
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# Colorado Health Law Symposium

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# AGENDA

*Thursday, April 15, 2021: Ethics and Health Law*

**11:30 – 11:35 am**

**Welcome and Introduction**

*Extended by **Matt Ullrich, Esq.**, Associate Counsel, Colorado Permanente Medical Group, P.C., Symposium Program Planning Committee Chair, and Chair of the Colorado Bar Association Health Law Section*

**11:35 am – 12:25 pm**

**The Attorney Regulation Process and Common Ethical Issues**

Assistant Regulation Counsel Catherine “Cat” Shea will present on The Attorney Regulation Process and Common Ethical Issues, including the disciplinary investigation process and statistics, practice pointers, attorney well-being, and recently adopted Colorado Rules of Professional Conduct.

*Presented by **Catherine “Cat” Shea, Esq.**, Assistant Attorney Regulation Counsel, Office of Attorney Regulation Counsel, Colorado Supreme Court*

**Submitted for 1 Ethics Credit**

**12:30 – 1:45 pm**

**Stress Hardiness, Grit & Resiliency in the Legal Profession**

The practice of law is stressful on a “good day,” and becoming more stressful during these uncertain & changing times. Learn how to make “stress work for you” from a neurobiological and neurophysiological perspective and how to build resiliency to avoid the physical, emotional, and cognitive effects of stress.

*Presented by **Amy Kingery, MBA, LCSW, LAC**, Colorado Lawyer Assistance Program (COLAP)*

**Submitted for 1.5 Ethics Credits**

**1:45 pm**

**Adjourn**

*Thursday, April 22, 2021: Current Hot Topics*

**11:30 – 11:35 am**

**Welcome and Introduction**

*Extended by **Jessica Belle, Esq.**, Senior Corporate Counsel, Nephrology Practice Solutions, DaVita, Symposium Program Planning Committee*

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**11:35 am – 12:25 pm**

**Stark and Anti-Kickback Statute Updates – Final Stark and Safeharbor New Regulations**

On November 20, 2020, CMS issued a long-awaited final rule for the Medicare Physician Self-Referral Law (Stark Law). On the same day, the OIG released a final rule which amends various safe harbors to the Federal Anti-Kickback Statute (AKS). These new rules originated from the DHHS Regulatory Sprint to Coordinated Care, which has the purpose of reducing regulatory burdens on the healthcare industry and incentivizing coordinated care. The rules adopt important new value-based exceptions to the Stark Law and similar AKS safe harbors. The rules also finalize or modify exceptions/safe harbors relating to cybersecurity, electronic health records, and other matters. Additionally, the provisions of the final Stark rule attempt to resolve thorny issues relating to fair market value, commercial reasonableness, the value or volume of referrals, compensation that is set in advance, and technical noncompliance. Overall, the new rules are viewed as an important step toward modernizing Stark Law and Anti-Kickback Statute requirements while creating regulatory flexibility for value-based care arrangements. This presentation will highlight key aspects of the new rules and provide practice tips for compliance.

*Presented by **Meghan E. Pound, Esq.** and **Jennifer A. Sullivan, Esq.**, Caplan & Earnest LLC*

**12:30 – 1:30 pm**

**Artificial Intelligence in Healthcare – Strategies to Identify and Mitigate Privacy and Other Legal Risks**

Every day we hear about advances in artificial intelligence (AI) and how it will propel the healthcare industry forward to deliver care in new and innovative ways. This presentation will provide an introduction to AI, as well as legal issues that arise from the use of AI, algorithmic processing of personal information, and legal principles to resolve those issues. The panel will also discuss some examples of AI in the healthcare industry and questions that may soon arise as AI becomes more common in healthcare.

*Presented by **Chris Achatz, Esq.**, Koenig Oelsner Taylor Schoenfeld & Gaddis PC, **James Theiss, Esq.**, Senior Corporate Counsel and Director, Privacy and Security, DaVita, and **Nolan Young, Esq.**, Vice President, Associate General Counsel, Health Care Innovation, DaVita*

**1:30 pm**

**Adjourn**

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*Thursday, April 29, 2021: Government Updates*

**11:30 – 11:35 am**

**Welcome and Introduction**

*Extended by Ann C. McCullough, Esq., Polsinelli PC,  
Symposium Program Planning Committee*

**11:35 am – 12:25 pm**

**Report from Inside the Beltway: What's Going on (or Not)?**

-President's Budget Proposal and Outlook in Congress  
-Prescription Drug Pricing and Surprise Medical Billing

*Presented by Julius W. Hobson, Jr., Senior Policy Advisor,  
Polsinelli PC*

**12:30 – 12:40 pm**

**Announcements and a Thank You to Sponsors**

**12:40 – 1:30 pm**

**State of the Healthcare Industry: Impact on Your Practice**

- Changing Patient Demographics  
- Who's Providing the Care  
- Data , Data, Data  
- Health Care of All  
- Artificial Intelligence

*Presented by David S. Cade, Executive Vice President/CEO,  
American Health Lawyers Association*

**1:30 pm**

**Adjourn**

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# **BIOGRAPHICAL INFORMATION**

## **PLANNING COMMITTEE**

**Matt Ullrich, Esq.**, currently serves as the Associate General Counsel for Colorado Permanente Medical Group, P.C. (CPMG). Prior to his role at CPMG, Matt was an Associate health law attorney at Caplan and Earnest, LLC and a Contracts and Operations Specialist at Colorado Medicaid. Matt is the current Chair of the Health Law Section of the Colorado Bar Association.

**Jessica Belle, Esq.**

**Renee Marr, Esq.**

**Ann C. McCullough, Esq.**, offers a practical perspective to health care clients. She has a clinical background and 30 years of health law experience, both in private practice and as in-house counsel. Ann has a deep understanding of the operational aspects of relating to hospitals and other health care providers, including hospital-physician financial arrangements, physician employment, medical staff, health facility licensure, telemedicine, EMTALA, contracting, telehealth and regulatory compliance.

**Kathleen Snow Sutton, Esq.**

## **PROGRAM FACULTY:**

**Chris Achatz, Esq.**, represents companies in structuring and negotiating complex technology and data-related transactions, including data privacy and security matters. He has worked on a wide variety of commercial agreements, and his data privacy and security practice involves advising his clients on industry-specific regulations and standards that govern the responsible collection, use, and processing of their customers' personal information. Chris is a Certified Information Privacy Professional (CIPP/US).

**David S. Cade** is the Executive Vice President/CEO of the American Health Lawyers Association (AHLA), the nation's largest nonpartisan educational organization devoted to legal issues in the health care field. The Association's more than 14,000 members practice in a variety of settings in the health care community. He joined AHLA in March 2015. Mr. Cade's broad leadership experience in the health law profession includes a 14-year role as Deputy General Counsel at the U.S. Department of Health and Human Services (HHS), where he supported program policy and developed legal positions to expand health insurance and coverage options for Medicare beneficiaries, as well as established creative solutions to support Medicaid program expansions. During his 28 year career at HHS, he also served as the Acting General Counsel and he was the Director of the Centers for Medicare and

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Medicaid Services' Family and Children's Health Programs Group and Acting Deputy Director of the Medicaid Bureau. Mr. Cade also served as a working group member of the Clinton White House Task Force on Health Care Reform. Prior to accepting the top staff position at AHLA in 2015, Mr. Cade was a Shareholder in the Health Care and Public Policy Practices at the national law firm Polsinelli, P.C. in Washington, DC, where he advised large hospitals, health systems, associations, corporations, and community providers. Mr. Cade also served for six years on AHLA's Board of Directors (2009-2015), where his work included efforts to increase the diversity of the Association's members and leaders as well as to broaden participation among public sector lawyers, non-lawyer health care practitioners, health care liability experts, and academicians. David Cade is a tireless advocate for diversity and inclusion in his field and for health care delivery systems and has advocated for greater focus around the issue during his time in both the public and private sectors. Throughout his career he has created a collaborative environment where public and private sector parties can come together to discuss the most challenging legal and policy issues impacting the health care system including financing, reimbursement, compliance, quality and patient centered care, fraud and abuse, corporate governance, emergency preparedness, and numerous coverage and eligibility policy issues. Mr. Cade earned his law degree from the University of Maryland School of Law and his B.A. from The College of William and Mary. He is a member of several bar associations including the District of Columbia Bar, Commonwealth of Pennsylvania Bar, The U.S. Supreme Court Bar, the United States Court of Appeals for the District of Columbia Circuit, and several other Circuit courts.

**Julius W. Hobson, Jr.,** (B.A., Howard University, M.A., George Washington University) is Senior Policy Advisor, Polsinelli, where he concentrates on assisting clients with legislative and regulatory advocacy concerning health care, appropriations, budget, taxes, and various other public policy issues. With more than 45 years' experience working with the U.S. Congress and the Federal Executive Branch, he has served as Director, Division of Congressional Affairs, American Medical Association (AMA) where he managed the AMA's interaction with the Congress. Mr. Hobson previously served on the staff of Senator Charles Robb [D-VA], where he was responsible for budget, financial and economic issues. He previously served in the Executive Office of the District of Columbia Mayor where he was responsible for coordinating the city's relations with the Congress and the Federal Executive Branch. Mr. Hobson served in the U.S. House of Representatives as a subcommittee Staff Director and as Chief of Staff to a Member of the House. He also handled Congressional Affairs for Howard University. Mr. Hobson served a four-year term as an elected member of the D.C. Board of Education, during which he served a term as Vice President. He is an adjunct professor at the Graduate School of Political Management, George Washington University, where he has taught the graduate course on lobbying since 1994 and teaches Legislative Writing and Research. Mr. Hobson previously taught Advanced Strategy Lobbying, Fundamentals of Political Management, and Electoral and Legislative Processes.

**Amy Kingery, MBA, LCSW, LAC,** is the Assistant Director for the Colorado Lawyer Assistance Program (COLAP). She is a Colorado native with over 15 years' experience serving individuals, families and professionals working within the intersections of the courts, child welfare, behavioral health and trauma. Amy received her BA from the University of

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Hawai'i-Hilo and her MSW and MBA from Newman University. Ms. Kingery is a licensed clinical social worker and licensed addiction counselor in the state of Colorado.

**Meghan E. Pound, Esq.,** leads Caplan & Earnest's Health Law section. She has represented clients in federal and state courts, at both the trial and appellate levels, in administrative proceedings and in arbitrations. Ms. Pound has handled a wide variety of internal investigations, and represented individuals, partnerships, public entities, nonprofit corporations, and hospitals. Additionally, her work includes a wide variety of litigation matters defending hospitals and other health care practices accused of civil rights violations, employment discrimination, negligence relating to professional review, and false claims act violations.

**Catherine "Cat" Shea, Esq.,** is an Assistant Regulation Counsel for the Colorado Supreme Court Office of Attorney Regulation Counsel. Between 2013 and 2016, she worked in the Office's Trial Division, investigating and prosecuting attorney discipline and disability, law examiner, magistrate, and judicial matters at trial and in appellate proceedings. In 2016, Cat moved to the Office's Intake Division, which reviews all requests for investigation filed with the Office. She received her undergraduate degree from Western Kentucky University and her law degree from the University of Michigan Law School. After graduation, she clerked for the Honorable Robert D. Hawthorne at the Colorado Court of Appeals. Prior to joining the Office of Attorney Regulation Counsel, Cat served as an Assistant Attorney General for the State of Colorado in the Business & Licensing Section for nearly five years. She is past president of the Colorado Women's Bar Association ("CWBA") and has served on its Board of Directors since 2010. Cat is also a 2015 graduate of the Colorado Bar Association's Leadership Training Program, known as COBALT.

**Jennifer A. Sullivan, Esq.,** is a member of Caplan & Earnest, where her practice focuses on transactional and regulatory compliance as part of the firm's health law section. Her practice at Caplan & Earnest is limited to the representation of healthcare organizations, including hospitals and other healthcare facilities, management services organizations, practitioners, and provider networks. With more than 30 years of healthcare experience, her practice areas include general counsel services, advising governing boards, management services relationships, acquisitions and other complex transactions, licensure, health program enrollment, reimbursement, and regulatory compliance (including Stark Law, Anti-Kickback Statute, overpayment, and HIPAA issues).

**James Theiss, Esq.,** is a Director and Senior Corporate Counsel at DaVita, Inc. where he works on the leadership team of the legal department's Privacy Office. James supports DaVita's cross-lane committee for Artificial Intelligence and Predictive Analytics with privacy and cybersecurity guidance. Additionally, James oversees various aspects of DaVita's privacy program, including incident response, contract negotiations, and operational support to the IT and HR functions. James is a Privacy Law Specialist as designated by the IAPP and accredited by the ABA.

**Nolan Young, Esq.,** is Vice President and Associate General Counsel at DaVita, Inc. where he leads the DaVita legal department's health care strategy and innovation team and coordinates cross lane legal support for Artificial Intelligence and Predictive Analytics.

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In addition to supporting DaVita's strategy and innovation teams, Nolan provides guidance on health care regulatory and fraud and abuse laws. Prior to joining DaVita in 2014, Nolan practiced health care law in the Washington, D.C. offices of two large international law firms. Nolan's practice included defending health care providers and suppliers in government investigations, *qui tam* and government enforcement actions, and counseling clients on complex health regulatory concerns.

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# **SECTION 1**

## **The Attorney Regulation Process and Common Ethical Issues**



*Presented by*

**Catherine “Cat” Shea, Esq.**  
Assistant Attorney Regulation Counsel  
Office of Attorney Regulation Counsel, Colorado  
Supreme Court  
Denver, CO

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# AMERICAN BAR ASSOCIATION

STANDING COMMITTEE ON ETHICS AND PROFESSIONAL RESPONSIBILITY

**Formal Opinion 498**

**March 10, 2021**

## **Virtual Practice**

*The ABA Model Rules of Professional Conduct permit virtual practice, which is technologically enabled law practice beyond the traditional brick-and-mortar law firm.<sup>1</sup> When practicing virtually, lawyers must particularly consider ethical duties regarding competence, diligence, and communication, especially when using technology. In compliance with the duty of confidentiality, lawyers must make reasonable efforts to prevent inadvertent or unauthorized disclosures of information relating to the representation and take reasonable precautions when transmitting such information. Additionally, the duty of supervision requires that lawyers make reasonable efforts to ensure compliance by subordinate lawyers and nonlawyer assistants with the Rules of Professional Conduct, specifically regarding virtual practice policies.*

### **I. Introduction**

As lawyers increasingly use technology to practice virtually, they must remain cognizant of their ethical responsibilities. While the ABA Model Rules of Professional Conduct permit virtual practice, the Rules provide some minimum requirements and some of the Comments suggest best practices for virtual practice, particularly in the areas of competence, confidentiality, and supervision. These requirements and best practices are discussed in this opinion, although this opinion does not address every ethical issue arising in the virtual practice context.<sup>2</sup>

### **II. Virtual Practice: Commonly Implicated Model Rules**

This opinion defines and addresses virtual practice broadly, as technologically enabled law practice beyond the traditional brick-and-mortar law firm.<sup>3</sup> A lawyer's virtual practice often occurs when a lawyer at home or on-the-go is working from a location outside the office, but a lawyer's practice may be entirely virtual because there is no requirement in the Model Rules that a lawyer

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<sup>1</sup> This opinion is based on the ABA Model Rules of Professional Conduct as amended by the ABA House of Delegates through August 2020. The laws, court rules, regulations, rules of professional conduct, and opinions promulgated in individual jurisdictions are controlling.

<sup>2</sup> Interstate virtual practice, for instance, also implicates Model Rule of Professional Conduct 5.5: Unauthorized Practice of Law; Multijurisdictional Practice of Law, which is not addressed by this opinion. See ABA Comm. on Ethics & Prof'l Responsibility, Formal Op. 495 (2020), stating that "[l]awyers may remotely practice the law of the jurisdictions in which they are licensed while physically present in a jurisdiction in which they are not admitted if the local jurisdiction has not determined that the conduct is the unlicensed or unauthorized practice of law and if they do not hold themselves out as being licensed to practice in the local jurisdiction, do not advertise or otherwise hold out as having an office in the local jurisdiction, and do not provide or offer to provide legal services in the local jurisdiction."

<sup>3</sup> See generally MODEL RULES OF PROFESSIONAL CONDUCT R. 1.0(c), defining a "firm" or "law firm" to be "a lawyer or lawyers in a partnership, professional corporation, sole proprietorship or other association authorized to practice law; or lawyers employed in a legal services organization on the legal department of a corporation or other organization." Further guidance on what constitutes a firm is provided in Comments [2], [3], and [4] to Rule 1.0.

have a brick-and-mortar office. Virtual practice began years ago but has accelerated recently, both because of enhanced technology (and enhanced technology usage by both clients and lawyers) and increased need. Although the ethics rules apply to both traditional and virtual law practice,<sup>4</sup> virtual practice commonly implicates the key ethics rules discussed below.

A. *Commonly Implicated Model Rules of Professional Conduct*

1. Competence, Diligence, and Communication

Model Rules 1.1, 1.3, and 1.4 address lawyers' core ethical duties of competence, diligence, and communication with their clients. Comment [8] to Model Rule 1.1 explains, "To maintain the requisite knowledge and skill [to be competent], a lawyer should keep abreast of changes in the law and its practice, *including the benefits and risks associated with relevant technology*, engage in continuing study and education and comply with all continuing legal education requirements to which the lawyer is subject." (*Emphasis added*). Comment [1] to Rule 1.3 makes clear that lawyers must also "pursue a matter on behalf of a client despite opposition, obstruction or personal inconvenience to the lawyer, and take whatever lawful and ethical measures are required to vindicate a client's cause or endeavor." Whether interacting face-to-face or through technology, lawyers must "reasonably consult with the client about the means by which the client's objectives are to be accomplished; . . . keep the client reasonably informed about the status of the matter; [and] promptly comply with reasonable requests for information. . . ." <sup>5</sup> Thus, lawyers should have plans in place to ensure responsibilities regarding competence, diligence, and communication are being fulfilled when practicing virtually.<sup>6</sup>

2. Confidentiality

Under Rule 1.6 lawyers also have a duty of confidentiality to all clients and therefore "shall not reveal information relating to the representation of a client" (absent a specific exception, informed consent, or implied authorization). A necessary corollary of this duty is that lawyers must at least "make reasonable efforts to prevent the inadvertent or unauthorized disclosure of, or unauthorized access to, information relating to the representation of a client."<sup>7</sup> The following non-

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<sup>4</sup> For example, if a jurisdiction prohibits substantive communications with certain witnesses during court-related proceedings, a lawyer may not engage in such communications either face-to-face or virtually (e.g., during a trial or deposition conducted via videoconferencing). *See, e.g.*, MODEL RULES OF PROF'L CONDUCT R. 3.4(c) (prohibiting lawyers from violating court rules and making no exception to the rule for virtual proceedings). Likewise, lying or stealing is no more appropriate online than it is face-to-face. *See, e.g.*, MODEL RULES OF PROF'L CONDUCT R. 1.15; MODEL RULES OF PROF'L CONDUCT R. 8.4(b)-(c).

<sup>5</sup> MODEL RULES OF PROF'L CONDUCT R. 1.4(a)(2) – (4).

<sup>6</sup> Lawyers unexpectedly thrust into practicing virtually must have a business continuation plan to keep clients apprised of their matters and to keep moving those matters forward competently and diligently. ABA Comm. on Ethics & Prof'l Responsibility, Formal Op. 482 (2018) (discussing ethical obligations related to disasters). Though virtual practice is common, if for any reason a lawyer cannot fulfill the lawyer's duties of competence, diligence, and other ethical duties to a client, the lawyer must withdraw from the matter. MODEL RULES OF PROF'L CONDUCT R. 1.16. During and following the termination or withdrawal process, the "lawyer shall take steps to the extent reasonably practicable to protect a client's interests, such as giving reasonable notice to the client, allowing time for employment of other counsel, surrendering papers and property to which the client is entitled and refunding any advance payment of fee or expense that has not been earned or incurred." MODEL RULES OF PROF'L CONDUCT R. 1.16(d).

<sup>7</sup> MODEL RULES OF PROF'L CONDUCT R. 1.6(c).

exhaustive list of factors may guide the lawyer's determination of reasonable efforts to safeguard confidential information: "the sensitivity of the information, the likelihood of disclosure if additional safeguards are not employed, the cost of employing additional safeguards, the difficulty of implementing the safeguards, and the extent to which the safeguards adversely affect the lawyer's ability to represent clients (e.g., by making a device or important piece of software excessively difficult to use)."<sup>8</sup> As ABA Formal Op. 477R notes, lawyers must employ a "fact-based analysis" to these "nonexclusive factors to guide lawyers in making a 'reasonable efforts' determination."

Similarly, lawyers must take reasonable precautions when transmitting communications that contain information related to a client's representation.<sup>9</sup> At all times, but especially when practicing virtually, lawyers must fully consider and implement reasonable measures to safeguard confidential information and take reasonable precautions when transmitting such information. This responsibility "does not require that the lawyer use special security measures if the method of communication affords a reasonable expectation of privacy."<sup>10</sup> However, depending on the circumstances, lawyers may need to take special precautions.<sup>11</sup> Factors to consider to assist the lawyer in determining the reasonableness of the "expectation of confidentiality include the sensitivity of the information and the extent to which the privacy of the communication is protected by law or by a confidentiality agreement."<sup>12</sup> As ABA Formal Op. 477R summarizes, "[a] lawyer generally may transmit information relating to the representation of a client over the Internet without violating the Model Rules of Professional Conduct where the lawyer has undertaken reasonable efforts to prevent inadvertent or unauthorized access."

### 3. Supervision

Lawyers with managerial authority have ethical obligations to establish policies and procedures to ensure compliance with the ethics rules, and supervisory lawyers have a duty to make reasonable efforts to ensure that subordinate lawyers and nonlawyer assistants comply with the applicable Rules of Professional Conduct.<sup>13</sup> Practicing virtually does not change or diminish this obligation. "A lawyer must give such assistants appropriate instruction and supervision concerning the ethical aspects of their employment, particularly regarding the obligation not to disclose information relating to representation of the client, and should be responsible for their work product."<sup>14</sup> Moreover, a lawyer must "act competently to safeguard information relating to the representation of a client against unauthorized access by third parties and against inadvertent

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<sup>8</sup> MODEL RULES OF PROF'L CONDUCT R. 1.6 cmt. [18].

<sup>9</sup> MODEL RULES OF PROF'L CONDUCT R. 1.6 cmt. [19].

<sup>10</sup> *Id.*

<sup>11</sup> The opinion cautions, however, that "a lawyer may be required to take special security precautions to protect against the inadvertent or unauthorized disclosure of client information when required by an agreement with the client or by law, or when the nature of the information requires a higher degree of security." ABA Comm. on Ethics & Prof'l Responsibility, Formal Op. 477R (2017).

<sup>12</sup> MODEL RULES OF PROF'L CONDUCT R. 1.6 cmt. [19].

<sup>13</sup> MODEL RULES OF PROF'L CONDUCT R. 5.1 & 5.3. *See, e.g.*, ABA Comm. on Ethics & Prof'l Responsibility, Formal Op. 467 (2014) (discussing managerial and supervisory obligations in the context of prosecutorial offices). *See also* ABA Comm. on Ethics & Prof'l Responsibility, Formal Op. 483 n.6 (2018) (describing the organizational structures of firms as pertaining to supervision).

<sup>14</sup> MODEL RULES OF PROF'L CONDUCT R. 5.3 cmt. [2].

or unauthorized disclosure by the lawyer *or other persons who are participating in the representation of the client or who are subject to the lawyer's supervision.*"<sup>15</sup> The duty to supervise nonlawyers extends to those both within and outside of the law firm.<sup>16</sup>

### B. *Particular Virtual Practice Technologies and Considerations*

Guided by the rules highlighted above, lawyers practicing virtually need to assess whether their technology, other assistance, and work environment are consistent with their ethical obligations. In light of current technological options, certain available protections and considerations apply to a wide array of devices and services. As ABA Formal Op. 477R noted, a "lawyer has a variety of options to safeguard communications including, for example, using secure internet access methods to communicate, access and store client information (such as through secure Wi-Fi, the use of a Virtual Private Network, or another secure internet portal), using unique complex passwords, changed periodically, implementing firewalls and anti-Malware/Anti-Spyware/Antivirus software on all devices upon which client confidential information is transmitted or stored, and applying all necessary security patches and updates to operational and communications software." Furthermore, "[o]ther available tools include encryption of data that is physically stored on a device and multi-factor authentication to access firm systems." To apply and expand on these protections and considerations, we address some common virtual practice issues below.

#### 1. Hard/Software Systems

Lawyers should ensure that they have carefully reviewed the terms of service applicable to their hardware devices and software systems to assess whether confidentiality is protected.<sup>17</sup> To protect confidential information from unauthorized access, lawyers should be diligent in installing any security-related updates and using strong passwords, antivirus software, and encryption. When connecting over Wi-Fi, lawyers should ensure that the routers are secure and should consider using virtual private networks (VPNs). Finally, as technology inevitably evolves, lawyers should periodically assess whether their existing systems are adequate to protect confidential information.

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<sup>15</sup> MODEL RULES OF PROF'L CONDUCT R. 1.6 cmt. [18] (emphasis added).

<sup>16</sup> As noted in Comment [3] to Model Rule 5.3:

When using such services outside the firm, a lawyer must make reasonable efforts to ensure that the services are provided in a manner that is compatible with the lawyer's professional obligations. The extent of this obligation will depend upon the circumstances, including the education, experience and reputation of the nonlawyer; the nature of the services involved; the terms of any arrangements concerning the protection of client information; and the legal and ethical environments of the jurisdictions in which the services will be performed, particularly with regard to confidentiality. See also Rules 1.1 (competence), 1.2 (allocation of authority), 1.4 (communication with client), 1.6 (confidentiality), 5.4(a) (professional independence of the lawyer), and 5.5(a) (unauthorized practice of law).

<sup>17</sup> For example, terms and conditions of service may include provisions for data-soaking software systems that collect, track, and use information. Such systems might purport to own the information, reserve the right to sell or transfer the information to third parties, or otherwise use the information contrary to lawyers' duty of confidentiality.



## 2. Accessing Client Files and Data

Lawyers practicing virtually (even on short notice) must have reliable access to client contact information and client records. If the access to such “files is provided through a cloud service, the lawyer should (i) choose a reputable company, and (ii) take reasonable steps to ensure that the confidentiality of client information is preserved, and that the information is readily accessible to the lawyer.”<sup>18</sup> Lawyers must ensure that data is regularly backed up and that secure access to the backup data is readily available in the event of a data loss. In anticipation of data being lost or hacked, lawyers should have a data breach policy and a plan to communicate losses or breaches to the impacted clients.<sup>19</sup>

## 3. Virtual meeting platforms and videoconferencing

Lawyers should review the terms of service (and any updates to those terms) to ensure that using the virtual meeting or videoconferencing platform is consistent with the lawyer’s ethical obligations. Access to accounts and meetings should be only through strong passwords, and the lawyer should explore whether the platform offers higher tiers of security for businesses/enterprises (over the free or consumer platform variants). Likewise, any recordings or transcripts should be secured. If the platform will be recording conversations with the client, it is inadvisable to do so without client consent, but lawyers should consult the professional conduct rules, ethics opinions, and laws of the applicable jurisdiction.<sup>20</sup> Lastly, any client-related meetings or information should not be overheard or seen by others in the household, office, or other remote location, or by other third parties who are not assisting with the representation,<sup>21</sup> to avoid jeopardizing the attorney-client privilege and violating the ethical duty of confidentiality.

## 4. Virtual Document and Data Exchange Platforms

In addition to the protocols noted above (e.g., reviewing the terms of service and any updates to those terms), lawyers’ virtual document and data exchange platforms should ensure that

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<sup>18</sup> ABA Comm. on Ethics & Prof’l Responsibility, Formal Op. 482 (2018).

<sup>19</sup> See, e.g., ABA Comm. on Ethics & Prof’l Responsibility, Formal Op. 483 (2018) (“Even lawyers who, (i) under Model Rule 1.6(c), make ‘reasonable efforts to prevent the . . . unauthorized disclosure of, or unauthorized access to, information relating to the representation of a client,’ (ii) under Model Rule 1.1, stay abreast of changes in technology, and (iii) under Model Rules 5.1 and 5.3, properly supervise other lawyers and third-party electronic-information storage vendors, may suffer a data breach. When they do, they have a duty to notify clients of the data breach under Model Rule 1.4 in sufficient detail to keep clients ‘reasonably informed’ and with an explanation ‘to the extent necessary to permit the client to make informed decisions regarding the representation.’”).

<sup>20</sup> See, e.g., ABA Comm. on Ethics & Prof’l Responsibility, Formal Op. 01-422 (2001).

<sup>21</sup> Pennsylvania recently highlighted the following best practices for videoconferencing security:

- Do not make meetings public;
- Require a meeting password or use other features that control the admittance of guests;
- Do not share a link to a teleconference on an unrestricted publicly available social media post;
- Provide the meeting link directly to specific people;
- Manage screensharing options. For example, many of these services allow the host to change screensharing to “Host Only;”
- Ensure users are using the updated version of remote access/meeting applications.

Pennsylvania Bar Ass’n Comm. on Legal Ethics & Prof’l Responsibility, Formal Op. 2020-300 (2020) (citing an FBI press release warning of teleconference and online classroom hacking).

documents and data are being appropriately archived for later retrieval and that the service or platform is and remains secure. For example, if the lawyer is transmitting information over email, the lawyer should consider whether the information is and needs to be encrypted (both in transit and in storage).<sup>22</sup>

## 5. Smart Speakers, Virtual Assistants, and Other Listening-Enabled Devices

Unless the technology is assisting the lawyer's law practice, the lawyer should disable the listening capability of devices or services such as smart speakers, virtual assistants, and other listening-enabled devices while communicating about client matters. Otherwise, the lawyer is exposing the client's and other sensitive information to unnecessary and unauthorized third parties and increasing the risk of hacking.

## 6. Supervision

The virtually practicing managerial lawyer must adopt and tailor policies and practices to ensure that all members of the firm and any internal or external assistants operate in accordance with the lawyer's ethical obligations of supervision.<sup>23</sup> Comment [2] to Model Rule 5.1 notes that "[s]uch policies and procedures include those designed to detect and resolve conflicts of interest, identify dates by which actions must be taken in pending matters, account for client funds and property and ensure that inexperienced lawyers are properly supervised."

### a. Subordinates/Assistants

The lawyer must ensure that law firm tasks are being completed in a timely, competent, and secure manner.<sup>24</sup> This duty requires regular interaction and communication with, for example,

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<sup>22</sup> See, e.g., ABA Comm. on Ethics & Prof'l Responsibility, Formal Op. 477R (2017) (noting that "it is not always reasonable to rely on the use of unencrypted email").

<sup>23</sup> As ABA Formal Op. 477R noted:

In the context of electronic communications, lawyers must establish policies and procedures, and periodically train employees, subordinates and others assisting in the delivery of legal services, in the use of reasonably secure methods of electronic communications with clients. Lawyers also must instruct and supervise on reasonable measures for access to and storage of those communications. Once processes are established, supervising lawyers must follow up to ensure these policies are being implemented and partners and lawyers with comparable managerial authority must periodically reassess and update these policies. This is no different than the other obligations for supervision of office practices and procedures to protect client information.

<sup>24</sup> The New York County Lawyers Association Ethics Committee recently described some aspects to include in the firm's practices and policies:

- Monitoring appropriate use of firm networks for work purposes.
- Tightening off-site work procedures to ensure that the increase in worksites does not similarly increase the entry points for a data breach.
- Monitoring adherence to firm cybersecurity procedures (e.g., not processing or transmitting work across insecure networks, and appropriate storage of client data and work product).
- Ensuring that working at home has not significantly increased the likelihood of an inadvertent disclosure through misdirection of a transmission, possibly because the lawyer or nonlawyer was distracted by a child, spouse, parent or someone working on repair or maintenance of the home.

associates, legal assistants, and paralegals. Routine communication and other interaction are also advisable to discern the health and wellness of the lawyer's team members.<sup>25</sup>

One particularly important subject to supervise is the firm's bring-your-own-device (BYOD) policy. If lawyers or nonlawyer assistants will be using their own devices to access, transmit, or store client-related information, the policy must ensure that security is tight (e.g., strong passwords to the device and to any routers, access through VPN, updates installed, training on phishing attempts), that any lost or stolen device may be remotely wiped, that client-related information cannot be accessed by, for example, staff members' family or others, and that client-related information will be adequately and safely archived and available for later retrieval.<sup>26</sup>

Similarly, all client-related information, such as files or documents, must not be visible to others by, for example, implementing a "clean desk" (and "clean screen") policy to secure documents and data when not in use. As noted above in the discussion of videoconferencing, client-related information also should not be visible or audible to others when the lawyer or nonlawyer is on a videoconference or call. In sum, all law firm employees and lawyers who have access to client information must receive appropriate oversight and training on the ethical obligations to maintain the confidentiality of such information, including when working virtually.

#### b. Vendors and Other Assistance

Lawyers will understandably want and may need to rely on information technology professionals, outside support staff (e.g., administrative assistants, paralegals, investigators), and vendors. The lawyer must ensure that all of these individuals or services comply with the lawyer's obligation of confidentiality and other ethical duties. When appropriate, lawyers should consider use of a confidentiality agreement,<sup>27</sup> and should ensure that all client-related information is secure, indexed, and readily retrievable.

### 7. Possible Limitations of Virtual Practice

Virtual practice and technology have limits. For example, lawyers practicing virtually must make sure that trust accounting rules, which vary significantly across states, are followed.<sup>28</sup> The

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- Ensuring that sufficiently frequent "live" remote sessions occur between supervising attorneys and supervised attorneys to achieve effective supervision as described in [New York Rule of Professional Conduct] 5.1(c).

N.Y. County Lawyers Ass'n Comm. on Prof'l Ethics, Formal Op. 754-2020 (2020).

<sup>25</sup> See ABA MODEL REGULATORY OBJECTIVES FOR THE PROVISION OF LEGAL SERVICES para. I (2016).

<sup>26</sup> For example, a lawyer has an obligation to return the client's file when the client requests or when the representation ends. See, e.g., MODEL RULES OF PROF'L CONDUCT R. 1.16(d). This important obligation cannot be fully discharged if important documents and data are located in staff members' personal computers or houses and are not indexed or readily retrievable by the lawyer.

<sup>27</sup> See, e.g., Mo. Bar Informal Advisory Op. 20070008 & 20050068.

<sup>28</sup> See MODEL RULES OF PROF'L CONDUCT R. 1.15; See, e.g., ABA Comm. on Ethics & Prof'l Responsibility, Formal Op. 482 (2018) ("Lawyers also must take reasonable steps in the event of a disaster to ensure access to funds the lawyer is holding in trust. A lawyer's obligations with respect to these funds will vary depending on the circumstances. Even before a disaster, all lawyers should consider (i) providing for another trusted signatory on trust

lawyer must still be able, to the extent the circumstances require, to write and deposit checks, make electronic transfers, and maintain full trust-accounting records while practicing virtually. Likewise, even in otherwise virtual practices, lawyers still need to make and maintain a plan to process the paper mail, to docket correspondence and communications, and to direct or redirect clients, prospective clients, or other important individuals who might attempt to contact the lawyer at the lawyer's current or previous brick-and-mortar office. If a lawyer will not be available at a physical office address, there should be signage (and/or online instructions) that the lawyer is available by appointment only and/or that the posted address is for mail deliveries only. Finally, although e-filing systems have lessened this concern, litigators must still be able to file and receive pleadings and other court documents.

### **III. Conclusion**

The ABA Model Rules of Professional Conduct permit lawyers to conduct practice virtually, but those doing so must fully consider and comply with their applicable ethical responsibilities, including technological competence, diligence, communication, confidentiality, and supervision.

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#### **AMERICAN BAR ASSOCIATION STANDING COMMITTEE ON ETHICS AND PROFESSIONAL RESPONSIBILITY**

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accounts in the event of the lawyer's unexpected death, incapacity, or prolonged unavailability and (ii) depending on the circumstances and jurisdiction, designating a successor lawyer to wind up the lawyer's practice.”).

## Rule 1.5. Fees

(a) – (b) [NO CHANGE]

(c) A “contingent fee” is a fee for legal services under which compensation is to be contingent in whole or in part upon the successful accomplishment or disposition of the subject matter of the representation.

(1) The terms of a contingent fee agreement shall be communicated in writing before or within a reasonable time after commencing the representation and shall include the following information:

(i) The names of the lawyer and the client;

(ii) A statement of the nature of the claim, controversy or other matters with reference to which the services are to be performed, including each event triggering the lawyer’s right to compensation;

(iii) The method by which the fee is to be determined, including the percentage or amounts that will accrue to the lawyer in the event of settlement, trial or appeal, or other final disposition, and whether the contingent fee will be determined before or after the deduction of (A) costs and expenses advanced by the lawyer or otherwise incurred by the client, and (B) other amounts owed by the client and payable from amounts recovered;

(iv) A statement of the circumstances under which the lawyer may be entitled to compensation if the lawyer’s representation concludes, by discharge, withdrawal or otherwise, before the occurrence of an event that triggers the lawyer’s right to a contingent fee;

(v) A statement regarding expenses, including (A) an estimate of the expenses to be incurred, (B) whether the lawyer is authorized to advance funds for litigation-related expenses to be reimbursed to the lawyer from the recovery, and, if so, the amount of expenses the lawyer may advance without further approval, and (C) the client’s obligation, if any, to pay expenses if there is no recovery;

(vi) A statement regarding the possibility that a court will award costs or attorney fees against the client;

(vii) A statement regarding the possibility that a court will award costs or attorney fees in favor of the client, and, if so, how any such costs or attorney fees will be accounted for and handled;

(viii) A statement informing the client that if the lawyer wishes to hire a lawyer in another firm to assist in the handling of a matter (“associated counsel”), the lawyer will promptly inform the client in writing of the identity of the associated counsel, and that (A) the hiring of associated counsel will not increase the contingent fee, unless the client otherwise agrees in writing, and (B) the client has the right to disapprove the hiring of associated counsel and, if hired, to terminate the employment of associated counsel; and

(ix) A statement that other persons or entities may have a right to be paid from amounts recovered on the client’s behalf, for example when an insurer or a federal or state agency has paid money or benefits on behalf of a client in connection with the subject of the representation.

(2) A contingent fee agreement must be signed by the client and the lawyer.

(3) The lawyer shall retain a copy of the contingent fee agreement for seven years after the final resolution of the case, or the termination of the lawyer’s services, whichever first occurs.

- (4) No contingent fee agreement may be made
- (i) for representing a defendant in a criminal case,
  - (ii) in a domestic relations matter, where payment is contingent on the securing of a divorce or upon the amount of maintenance or child support, or property settlement in lieu of such amounts, or
  - (iii) in connection with any case or proceeding where a contingency method of a determination of attorney fees is otherwise prohibited by law.
- (5) Upon conclusion of a contingent fee matter, the lawyer shall provide the client a written disbursement statement showing the amount or amounts received, an itemization of costs and expenses incurred in handling of the matter, sums to be disbursed to third parties, including lawyers in other law firms, and computation of the contingent fee.
- (6) No contingent fee agreement shall be enforceable unless the lawyer has substantially complied with all of the provisions of this Rule.
- (7) The form Contingent Fee Agreement following the comment to this Rule may be used for contingent fee agreements and shall be sufficient to comply with paragraph (c)(1) of this Rule. The authorization of this form shall not prevent the use of other forms consistent with this Rule. Nothing in this Rule prevents a lawyer from entering into an agreement that provides for a contingent fee combined with one or more other types of fees, such as hourly or flat fees, provided that the agreement complies with this Rule insofar as the contingent fee is concerned.

**(d) – (h)** [NO CHANGE]

## **COMMENT**

**[1] – [2]** [NO CHANGE]

**[3]** Repealed.

**[4] – [5]** [NO CHANGE]

### *Contingent Fees*

**[6]** Contingent fees, whether based on the recovery or savings of money, or on a nonmonetary outcome, are subject to the reasonableness standard of paragraph (a) of this Rule. In determining whether a particular contingent fee is reasonable, or whether it is reasonable to charge any form of contingent fee, a lawyer must consider the factors that are relevant under the circumstances. Applicable law may impose limitations on contingent fees, such as a ceiling on the percentage allowable, or may require a lawyer to offer clients an alternative basis for the fee. *E.g.*, 28 U.S.C. § 2678 (limiting percentage of fees in Federal Tort Claims Act cases); C.R.S. § 8-43-403 (limiting percentage of contingent fee in certain worker’s compensation cases). The prohibition on contingent fees in certain domestic relations matters does not preclude a contract for a contingent fee for legal representation in connection with the recovery of post-judgment balances due under support, maintenance or other financial orders because such contracts do not implicate the same policy concerns.

[6A] The scope of representation in a contingent fee agreement should reflect whether the representation includes the handling of counterclaims, third-party claims to amounts recovered, and appeals.

[6B] A lawyer may include a provision in a contingent fee agreement setting forth the lawyer's agreement to reimburse the client for any attorney fees and costs awarded against the client. A provision in a contingent fee agreement in which the client must reimburse the lawyer for any attorney fees or costs awarded against the lawyer may be improper.

[6C] Nothing in this Rule prohibits a lawyer from arranging, in the contingent fee agreement or otherwise, for a third party to guarantee some or all of the financial obligations of the client in the contingent fee agreement.

[6D] Third parties often hold claims to amounts recovered by the lawyer on behalf of the client. The lawyer may be required, as a matter of professional ethics, to pay these amounts from the proceeds of a recovery and not to disburse them to the client.

[6E] A tribunal may award attorney fees to the client under a fee-shifting provision of a contract or statute or as a sanction for discovery violations or other litigation misconduct. The fee agreement may provide for a different allocation of such an award of fees as between the client and the lawyer depending on the circumstances giving rise to the award, such as whether the fees are awarded as a sanction for improper conduct that necessitated additional effort by the lawyer, or whether the fees are awarded under a contractual or statutory fee-shifting provision. This rule does not limit the ways in which clients and lawyers may contract to allocate awards of attorney fees; however, the lawyer must comply with the reasonableness standard of paragraph (a) of this Rule.

[6F] A conversion clause is a provision in a contingent fee agreement that notifies clients they may be liable for attorney fees in quantum meruit or on another alternate basis if the contingent fee agreement is terminated before the occurrence of the contingency. See, form Contingent Fee Agreement, ¶ (4). A conversion clause that requires payment of the alternate fee immediately upon termination, and regardless of the occurrence of the contingency, would discourage most clients from discharging their lawyer. Few clients have the financial means to pay a contingent fee from their own resources, with no guarantee of replenishment by a recovery from a third party. Therefore, a conversion clause that requires payment of the alternate fee immediately upon termination may be appropriate only if (a) the client is sophisticated in legal matters, has the means to pay the fee regardless of the occurrence of the contingency, and has specifically negotiated the conversion clause; and (b) the contingent fee agreement expressly requires payment of the alternate fee immediately upon termination.

[7] – [18] [NO CHANGE]

## FORM CONTINGENT FEE AGREEMENT

Dated \_\_\_\_\_, 20\_\_

\_\_\_\_\_ (Client), retains \_\_\_\_\_ (Lawyer) to perform the legal services described in paragraph (1) below. The Lawyer agrees to perform them faithfully and with due diligence.

(1) The claim, controversy, and other matters with reference to which the services are to be performed are: \_\_\_\_\_. The representation (will) (will not) [indicate which] include the handling of counterclaims, third-party claims to amounts recovered, and appeals.

(2) The contingency upon which compensation is to be paid is the Client's recovery of funds by settlement or judgment.

(3) The Client will pay the Lawyer \_\_\_ percent of the (gross amount collected) (net amount collected) [indicate which]. ("Gross amount collected" means the amount collected before any subtraction of expenses and disbursements) ("Net amount collected" means the amount of the collection remaining after subtraction of expenses and disbursements [including] [not including] costs or attorney fees awarded to an opposing party and against the Client.) [indicate which]. "The amount collected" (includes) (does not include) [indicate which] specially awarded attorney fees and costs awarded to the Client and against an opposing party.

(4) The Client is not to be liable to pay compensation otherwise than from amounts collected for the Client by the Lawyer, except as follows: In the event the Client terminates this contingent fee agreement without wrongful conduct by the Lawyer which would cause the Lawyer to forfeit any fee, or if the Lawyer justifiably withdraws from the representation of the Client, the Lawyer may ask the court or other tribunal to order that the Lawyer be paid a fee based upon the reasonable value of the services provided by the Lawyer. If the Lawyer and the Client cannot agree how the Lawyer is to be compensated in this circumstance, the Lawyer will request the court or other tribunal to determine: (1) whether the Client has been unfairly or unjustly enriched if the Client does not pay a fee to the Lawyer; and, if so (2) the amount of the fee owed, taking into account the nature and complexity of the Client's case, the time and skill devoted to the Client's case by the Lawyer, and the benefit obtained by the Client as a result of the Lawyer's efforts. Any such fee shall be payable only out of the gross recovery obtained by or on behalf of the Client and the amount of such fee shall not be greater than the fee that would have been earned by the Lawyer if the contingency described in this contingent fee agreement had occurred.

(5) A court or other tribunal may award costs or attorney fees to an opposing party and against the Client.

(6) The Client will be liable to the lawyer for reasonable expenses and disbursements. Such expenses and disbursements are estimated to be \$ \_\_\_\_\_. The Client authorizes the Lawyer to incur expenses and make disbursements up to a maximum of \$ \_\_\_\_\_. The



Lawyer will not exceed this limitation without the Client's further written authority. The Client will reimburse the Lawyer for such expenditures (upon receipt of a billing), (in specified installments), (upon final resolution), (etc.) [indicate which].

(7) If the Lawyer wishes to hire a lawyer in another firm to assist in the handling of a matter (called an "associated counsel"), the Lawyer will promptly inform the Client in writing of the identity of the associated counsel and that the hiring of associated counsel will not increase the contingent fee, unless the Client otherwise agrees in writing. The Client has a right to disapprove the hiring of associated counsel and to terminate the employment of associated counsel for any reason.

(8) Other persons or entities may have a right to be paid from amounts recovered on the Client's behalf. The Client (authorizes) (does not authorize) [indicate which] the Lawyer to pay from the amount collected the following: (e.g., all physicians, hospitals, subrogation claims and liens, etc.). The Lawyer may be legally required to pay the claims of third parties out of any monies collected for the Client, and not to disburse them to the Client. However, if the Client disputes the amount or validity of the third-party claim, the Lawyer may deposit the funds into the registry of an appropriate court for determination. Any amounts paid to third parties (will) (will not) [indicate which] be subtracted from the amount collected before computing the amount of the contingent fee under this agreement.

WE HAVE EACH READ THE ABOVE AGREEMENT BEFORE SIGNING IT.

(Signature of Client)

(Signature of Attorney)

**FINAL DISBURSEMENT STATEMENT FOR CONTINGENT FEE AGREEMENTS**

GROSS RECOVERY

\$ \_\_\_\_\_

Itemization of expenses incurred in handling of case:

\_\_\_\_\_ \$ \_\_\_\_\_

\_\_\_\_\_ \$ \_\_\_\_\_

\_\_\_\_\_ \$ \_\_\_\_\_

\_\_\_\_\_ \$ \_\_\_\_\_

Total Expenses \$ \_\_\_\_\_

Amount of Expenses

Advanced by Lawyer

\$ \_\_\_\_\_

Amount of Expenses

Paid by Client

\$ \_\_\_\_\_

NET RECOVERY

\$ \_\_\_\_\_

Computation of Contingent Fee:

\_\_\_\_\_ % of (Net) (Gross)

Recovery = \$ \_\_\_\_\_

Total Fee

(and expenses advanced

by Lawyer)\*

DISBURSEMENT TO CLIENT

\$ \_\_\_\_\_

\* (If fee is on "Net Recovery" and Lawyer has advanced expenses which are being reimbursed from the "gross recovery.")

(Signature of Lawyer)

(Signature of Client)

By signature Client acknowledges receipt of a copy of this disbursement statement.

## Rule 1.5. Fees

(a) – (g) [NO CHANGE]

(h) A “flat fee” is a fee for specified legal services for which the client agrees to pay a fixed amount, regardless of the time or effort involved.

(1) The terms of a flat fee shall be communicated in writing before or within a reasonable time after commencing the representation and shall include the following information:

(i) A description of the services the lawyer agrees to perform;

(ii) The amount to be paid to the lawyer and the timing of payment for the services to be performed;

(iii) If any portion of the flat fee is to be earned by the lawyer before conclusion of the representation, the amount to be earned upon the completion of specified tasks or the occurrence of specified events; and

(iv) The amount or the method of calculating the fees the lawyer earns, if any, should the representation terminate before completion of the specified tasks or the occurrence of specified events.

(2) If all or any portion of a flat fee is paid in advance of being earned and a dispute arises about whether the lawyer has earned all or part of the flat fee, the lawyer shall comply with Rule 1.15A(c) with respect to any portion of the flat fee that is in dispute.

(3) The form Flat Fee Agreement following the comment to this Rule may be used for flat fee agreements and shall be sufficient. The authorization of this form shall not prevent the use of other forms consistent with this Rule.

### COMMENT

#### Reasonableness of Fee and Expenses

[1] [NO CHANGE]

#### Basis or Rate of Fee

[2] When the lawyer has regularly represented a client, they ordinarily will have evolved an understanding concerning the basis or rate of the fee and the expenses for which the client will be responsible, but when there has been a change from their previous understanding the basis or rate of the fee should be promptly communicated in writing. In a new client-lawyer relationship,

the basis or rate of the fee must be promptly communicated in writing to the client, but the communication need not take the form of a formal engagement letter or agreement, and it need not be signed by the client. Moreover, it is not necessary to recite all the factors that underlie the basis of the fee, but only those that are directly involved in its computation. It is sufficient, for example, to state that the basic rate is an hourly charge or a fixed amount or an estimated amount, to identify the factors that may be taken into account in finally fixing the fee, or to furnish the client with a simple memorandum or the lawyer's customary fee schedule. When developments occur during the representation that render an earlier communication substantially inaccurate, a revised written communication should be provided to the client. All flat fee arrangements must be in writing and must comply with paragraph (h) of this Rule. All contingent fee arrangements must be in writing, regardless of whether the client-lawyer relationship is new or established. See C.R.C.P., Ch. 23.3, Rule 1.

[3] – [4] [NO CHANGE]

[5] A fee agreement may not be made whose terms might induce the lawyer improperly to curtail services for the client or perform them in a way contrary to the client's interest. For example, a lawyer should not enter into an agreement whereby services are to be provided only up to a stated amount when it is foreseeable that more extensive services probably will be required, unless the situation is adequately explained to the client. Otherwise, the client might have to bargain for further assistance in the midst of a proceeding or transaction. However, it is proper to define the extent of services in light of the client's ability to pay. A lawyer should not exploit a fee arrangement based primarily on hourly charges by using wasteful procedures.

[6] – [10] [NO CHANGE]

[11] To make a determination of when an advance fee is earned, the written statement of the basis or rate of the fee, when required by Rule 1.5(b) or (h), should include a description of the benefit or service that justifies the lawyer's earning the fee, the amount of the advance unearned fee, as well as a statement describing when the fee is earned. Whether a lawyer has conferred a sufficient benefit to earn a portion of the advance fee will depend on the circumstances of the particular case. The circumstances under which a fee is earned should be evaluated under an objective standard of reasonableness. Rule 1.5(a).

[12] Advances of unearned fees, including advances of all or a portion of a flat fee, are those funds the client pays for specified legal services that the lawyer has agreed to perform in the future. Pursuant to Rule 1.5(f), the lawyer must deposit an advance of unearned fees in the lawyer's trust account. The funds may be earned only as the lawyer performs specified legal services or confers benefits on the client as provided for in the written statement of the basis of the fee, if a written statement is required by Rule 1.5(b). See also Restatement (Third) of the Law Governing Lawyers §§ 34, 38 (1998). Rule 1.5(f) does not prevent a lawyer from entering into these types of arrangements.

[13] [NO CHANGE]

[14] A lawyer and client may agree that a flat fee or a portion of a flat fee is earned in various ways. For example, the lawyer and client may agree to an advance flat fee that will be earned in

whole or in part based upon the lawyer’s completion of specific tasks or the occurrence of specific events, regardless of the precise amount of the lawyer’s time involved. For instance, in a criminal defense matter, a lawyer and client may agree that the lawyer earns portions of the flat fee upon the lawyer’s entry of appearance, initial advisement, review of discovery, preliminary hearing, pretrial conference, disposition hearing, motions hearing, trial, and sentencing. Similarly, in a trusts and estates matter, a lawyer and client may agree that the lawyer earns portions of the flat fee upon client consultation, legal research, completing the initial draft of testamentary documents, further client consultation, and completing the final documents.

[15] The portions of the advance flat fee earned as each such event occurs need not be in equal amounts. However, the fees attributed to each event should reflect a reasonable estimate of the proportionate value of the legal services the lawyer provides in completing each designated event to the anticipated legal services to be provided on the entire matter. See Rule 1.5(a); Feiger, Collison & Killmer v. Jones, 926 P.2d 1244, 1252-53 (Colo. 1996) (client’s sophistication is relevant factor).

[16] “[A]n ‘engagement retainer fee’ is a fee paid, apart from any other compensation, to ensure that a lawyer will be available for the client if required. An engagement retainer must be distinguished from a lump-sum fee [*i.e.*, a flat fee] constituting the entire payment for a lawyer’s service in a matter and from an advance payment from which fees will be subtracted (see § 38, Comment g). A fee is an engagement retainer only if the lawyer is to be additionally compensated for actual work, if any, performed.” Restatement (Third) of the Law Governing Lawyers § 34 Comment e. An engagement retainer fee agreement must comply with Rule 1.5(a), (b), and (g), and should expressly include the amount of the engagement retainer fee, describe the service or benefit that justifies the lawyer’s earning the engagement retainer fee, and state that the engagement retainer fee is earned upon receipt. As defined above, an engagement retainer fee will be earned upon receipt because the lawyer provides an immediate benefit to the client, such as forgoing other business opportunities by making the lawyer’s services available for a given period of time to the exclusion of other clients or potential clients, or by giving priority to the client’s work over other matters.

[17] – [18] [NO CHANGE]

### **Form Flat Fee Agreement**

The client \_\_\_\_\_ (“Client”) retains \_\_\_\_\_ (“Lawyer” [or “Firm”]) to perform the legal services specified in Section I, below, for a flat fee as described below.

#### **I. Legal Services to Be Performed.**

In exchange for the fee described in this Agreement, Lawyer will perform the following legal services (“Services”): [*Insert specific description of the scope and/or objective of the*

*representation. Examples:* Represent Client in DUI criminal case in Jefferson County; Prepare a Will [or Power of Attorney or contract]]

**II. Flat Fee.**

This is a flat fee agreement. Client will pay Lawyer [or Firm] \$\_\_\_\_\_ for Lawyer's [or Firm's] performance of the Services described in Section I, above, plus costs as described in Section VI, below. Client understands that Client is NOT entering into an hourly fee arrangement. This means that Lawyer [or Firm] will devote such time to the representation as is necessary, but the Lawyer's [or Firm's] fee will not be increased or decreased based upon the number of hours spent.

**III. When Fee Is Earned.**

The flat fee will be earned in increments, as follows:

Description of increment: \_\_\_\_\_ Amount earned: \_\_\_\_\_

Description of increment: \_\_\_\_\_ Amount earned: \_\_\_\_\_

Description of increment: \_\_\_\_\_ Amount earned: \_\_\_\_\_

Description of Increment: \_\_\_\_\_ Amount earned: \_\_\_\_\_

Description of increment: \_\_\_\_\_ Amount earned: \_\_\_\_\_

[*Alternatively:* The flat fee will be earned when Lawyer [or Firm] provides Client with [*Select one:* the Will, the Power of Attorney, the contract, *other specified description of work*].

**IV. When Fee Is Payable.**

Client shall pay Lawyer [or Firm] [*Select one:* in advance, as billed, or as the services are completed]. Fees paid in advance shall be placed in Lawyer's [or Firm's] trust account and shall

remain the property of Client until they are earned. When the fee or part of the fee is earned pursuant to this Agreement, it becomes the property of Lawyer [or Firm].

**V. Right to Terminate Representation and Fees on Termination.**

Client has the right to terminate the representation at any time and for any reason, and Lawyer [or firm] may terminate the representation in accordance with Rule 1.16 of the Colorado Rules of Professional Conduct. In the event that Client terminates the representation without wrongful conduct by Lawyer [or Firm] that would cause Lawyer [or Firm] to forfeit any fee, or Lawyer [or Firm] justifiably withdraws in accordance with Rule 1.16 from representing Client, Client shall pay, and Lawyer [or Firm] shall be entitled to, the fee or part of the fee earned by Lawyer [or Firm] as described in Section I, above, up to the time of termination. In a litigation matter, Client shall pay, and Lawyer [or Firm] shall be entitled to, the fee or part of the fee earned up to the time when the court grants Lawyer's motion for withdrawal. If the representation is terminated between the completion of increments described in Section III above, Client shall pay a fee based on [an hourly rate of \$ \_\_\_\_\_] [the percentage of the task completed] [*other specified method*]. However, such fees shall not exceed the amount that would have been earned had the representation continued until the completion of the increment, and in any event all fees shall be reasonable.

**VI. Costs.**

Client is liable to Lawyer [or Firm] for reasonable expenses and disbursements. Examples of such expenses and disbursements are fees payable to the Court and expenses involved in preparing exhibits. Such expenses and disbursements are estimated to be \$ \_\_\_\_\_. Client authorizes Lawyer [or Firm] to incur expenses and disbursements up to a maximum of \$ \_\_\_\_\_, which limitation will not be exceeded without Client's further written authorization. Client shall reimburse Lawyer for such expenditures [*Select one*: upon receipt of a billing, in specified installments, or upon completion of the Services].

Dated: \_\_\_\_\_



CLIENT:

ATTORNEY [FIRM]:

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Signature

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Signature

## **Rule 8.4. Misconduct**

It is professional misconduct for a lawyer to:

(a) – (f) [NO CHANGE]

(g) engage in conduct, in the representation of a client, that exhibits or is intended to appeal to or engender bias against a person on account of that person's race, gender, religion, national origin, disability, age, sexual orientation, or socioeconomic status, whether that conduct is directed to other counsel, court personnel, witnesses, parties, judges, judicial officers, or any persons involved in the legal process;

(h) engage in any conduct that directly, intentionally, and wrongfully harms others and that adversely reflects on a lawyer's fitness to practice law; or

(i) engage in conduct the lawyer knows or reasonably should know constitutes sexual harassment where the conduct occurs in connection with the lawyer's professional activities.

### **COMMENT**

[1]-[5] [NO CHANGE]

[5A] Sexual harassment may include, but is not limited to, sexual advances, requests for sexual favors, and other verbal or physical conduct of a sexual nature that a reasonable person would perceive as unwelcome. The substantive law of employment discrimination, including anti-harassment statutes, regulations, and case law, may guide, but does not limit, application of paragraph (i). "Professional activities" are not limited to those that occur in a client-lawyer relationship.



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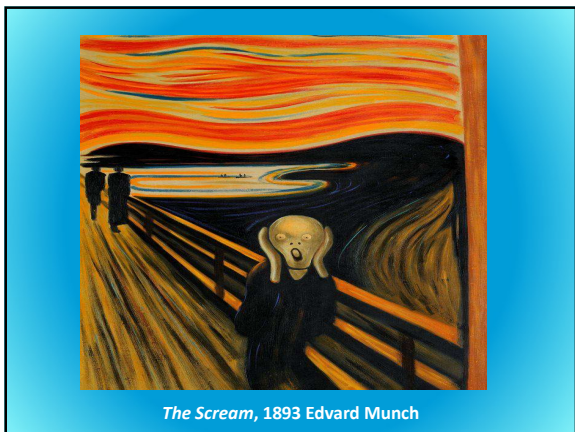
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**THE OFFICE OF ATTORNEY REGULATION COUNSEL**



Admissions  
 Registration  
 Continuing Judicial and Legal Education  
 Unauthorized Practice of Law  
 Regulation of Attorneys (including magistrates):

- Diversion – practice management/alcohol monitoring
- Discipline
- Disability
- Inventory Counsel
- Client Protection Fund

Special Counsel to Commission on Judicial Discipline

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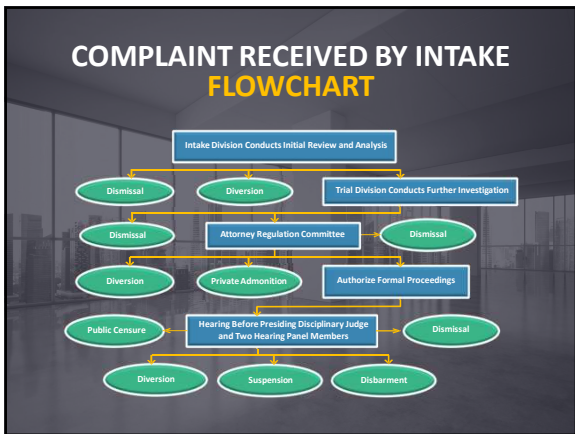
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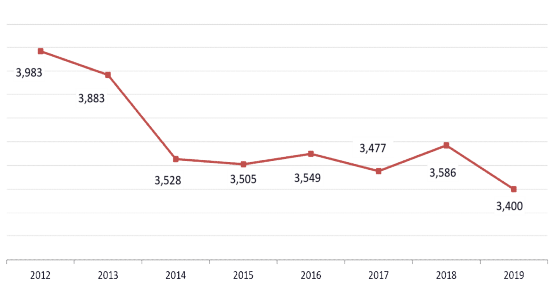


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## COMPLAINTS FILED FROM 2012 TO 2019




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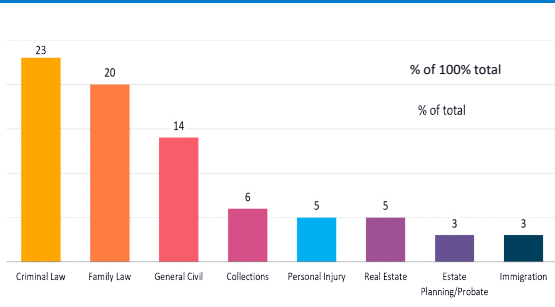
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## AREAS OF PRACTICE WITH THE MOST GRIEVANCES




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## ANALYZING COMPLAINTS

- Are the Rules implicated?
- Is there clear and convincing evidence?

And also...

- Lawyer's mental state and process




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## RESPONDING TO THE COMPLAINT

- Respond timely
- Provide relevant information and documents
- Don't make assumptions
- Consider hiring counsel



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## THE QUESTION IS, WHAT CAN YOU DO?

Is there a way to prevent complaints? What about better practice management?



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The Lawyer  
Self-Assessment  
Program

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## THE LAWYER SELF-ASSESSMENT PROGRAM

Go to [coloradosupremecourt.com](http://coloradosupremecourt.com)

- Lawyer Self-Assessment Program

3 CLE credits (both general and ethics) are available for completing the Self-Assessment

- Affidavit is on the website, on the homepage under the "Lawyer Self-Assessment" tab

See also C.R.C.P. 256, The Colorado Lawyer Self-Assessment Program

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## CONFIDENTIALITY RULE 256



▲ C.R.C.P. 256,  
Adopted June 28, 2018

- Work on the self-assessment is confidential;
- OARC does not collect any individually-identifiable answers or user data;
- Conversations with a law practice reviewer to obtain feedback on assessment questions are confidential;
- Law practice reviewers who mentor a lawyer following self-assessment are not subject to Rule 8.3(a).

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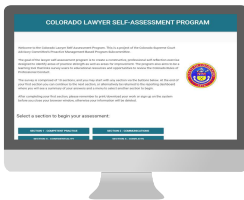
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## GETTING STARTED

- There are ten areas of assessment. Choose any to begin the survey.



- |                        |   |                       |
|------------------------|---|-----------------------|
| Competence             | • | Communications        |
| Confidentiality        | • | Access to Justice     |
| File Management        | • | Firm Management       |
| Fee Agreements         | • | Trust Accounts        |
| Wellness & Inclusivity | • | Conflicts of Interest |

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## ADDITIONAL RESOURCES



- Law journal articles, ethics opinions issued by the CBA's Ethics Committee or the ABA's Standing Committee on Professionalism, template forms, articles from legal periodicals, etc., are located at the end of each assessment

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## END OF ASSESSMENT REPORT



Displays answers. May download or print answers.

30 days to complete the entire assessment after you begin.

At end of report, users receive a comprehensive bibliography of educational resources.

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## EXAMPLE OF SECTION REPORT

**ASSESSMENT REPORT**

SECTION 1: COMMUNICATIONS    SECTION 2: COMMUNICATIONS    SECTION 3: COMMUNICATIONS    SECTION 4: COMMUNICATIONS    SECTION 5: COMMUNICATIONS    SECTION 6: COMMUNICATIONS    SECTION 7: COMMUNICATIONS    SECTION 8: COMMUNICATIONS

**OBJECTIVE 4 – Ensure you and your clients share the same understanding of the terms and scope of your engagement.**

Rule and practice considerations for Objective 4:  
Specify the client and lawyer's obligations under the terms and scope of the representation. Objectives for each party need to be clearly defined in order for the lawyer to abide by a client's decision as required by Code of Ethics 1.2. Further, the client desires to follow your advice. Documenting the recommendations you make complies with Code of Ethics 1.4(a) and (b), including that you explained the matter and allowed the client to make an informed decision. When the representation ends, it is important to communicate this well.

	YOUR ASSESSMENT
How would you assess your achievement of Objective 4?	4
BP 4.1: Best Practice: Have a standard engagement letter that explains the services you will provide, how and when your representation will terminate, that is specific to your firm, and expectations of the client / lawyer relationship.	N/A
BP 4.2: Best Practice: Inform clients of what is expected of them during the course of the representation. Do you employ this best practice?	YES
BP 4.3: Best Practice: Establish a formal protocol if a client refuses to follow your advice that includes documenting recommendations made to the client, reasons the recommendations were made, and an explanation of risks of not following your advice. Do you employ this best practice?	YES
BP 4.4: Best Practice: Maintain a template termination letter that you use and send to clients upon closure of files. Do you employ this best practice?	YES

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ARE YOU PREPARED FOR THE NEXT PHASE?

Case coverage Practice coverage



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WHAT IS YOUR CURRENT FILE STORAGE SYSTEM?



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MAYBE THIS?



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## NEXT STEPS

- Review Colo. RPC 1.16A and get rid of files you no longer need to keep.
- Periodically purge files pursuant to Colo. RPC 1.16A.
- Keep good financial records. *See* Colo. RPC 1.15D (seven years).
- Arrange coverage for cases AND for the practice.

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## ETHICAL CONSIDERATIONS FOR WORKING REMOTELY

- Colo. RPC 1.1: Competence
- Colo. RPC 1.3: Diligence
- Colo. RPC 1.4: Communication
- Colo. RPC 1.6: Confidentiality
- Colo. RPC 5.1: Supervising lawyers
- Colo. RPC 5.3: Supervising non-lawyer assistants

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**NEW ISSUE:  
IDENTITY THEFT**

- People assuming attorneys' identities, including their registration numbers, and creating websites holding themselves out as the attorney to defraud potential clients.

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**EXAMPLE:  
MEXICAN TIMESHARE RESALE**

Individual who purchased timeshare in Mexico and wants to sell it finds a fake website created by fraudsters using the name of a licensed US lawyer. Fraudsters pose as the lawyer and ask the seller to wire money for fees, taxes, etc., related to the sale. When the seller figures out something's wrong, they try to contact the real lawyer and potentially contact OARC to file a complaint. The lawyer is unaware of any of this and must now try to recover their identity, respond to requests for investigation, etc.

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**AMENDED RULE:  
Colo. RPC 1.5(c)**

Effective January 1, 2021

- Contingent fees
- Chapter 23.3 repealed
- Must be signed by both lawyer and client
- Copy must be retained for seven years
- Form Contingent Fee Agreement (sufficient, but not required)

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**NEW RULE:  
Colo. RPC 1.5(h)**

Effective January 31, 2019

- Flat fees must be placed in trust and billed against as earned
- To be earned, lawyer must convey some benefit to the client
- Hourly or task-based basis for earning fee
- Attorney fees are never “non-refundable”
- Form Flat Fee Agreement (sufficient, but not required)

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**AMENDED RULES:  
Colo. RPC 7.1-7.5**

Adopted September 10, 2020

- Rule 7.1: All but subsection (a)(1) eliminated
- Rule 7.2: No longer titled “Advertising”; addresses communications regarding a lawyer’s services more specifically
- Rule 7.3: expanded; includes definition of “solicitation”
- Rules 7.4 and 7.5: previous content removed and reserved for future use

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**NEW RULE:  
Colo. RPC 8.4(i)**

Effective September 19, 2019

- “It is professional misconduct for a lawyer to: . . .  
(i) engage in conduct the lawyer knows or reasonably should know constitutes sexual harassment where the conduct occurs in connection with the lawyer’s professional activities.”
- Comment [5A] addresses the definition of sexual harassment, but is not exclusive. Keep in mind that “professional activities” are not limited to the client-lawyer relationship.

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**THE PATH TO  
LAWYER WELL-BEING:**  
Practical Recommendations  
For Positive Change

THE REPORT OF THE  
NATIONAL TASK FORCE ON  
LAWYER WELL-BEING

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**TASK FORCE  
GENESIS**

*The Prevalence of Substance Use and Other Mental Health Concerns Among American Attorneys (the "Attorney Study")*

- P. R. Krill, R. Johnson, & L. Albert
- 10 J. Addiction Med. 46 (2016)

*Suffering in Silence: The Survey of Law Student Well-Being and the Reluctance of Law Students to Seek Help for Substance Use and Mental Health Concerns (the "Law Student Survey")*

- J. M. Organ, D. Jaffe, K. Bender
- 66 J. Legal Educ. 116 (2016)

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**ATTORNEY STUDY FINDINGS  
MENTAL HEALTH**

Depression	28%
Severe anxiety	19%
Suicidal thoughts in last year	11.5%

- ABA CoLAP/Hazelden Betty Ford Foundation study

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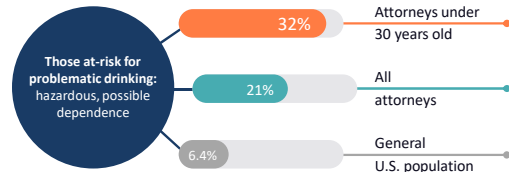
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## ATTORNEY STUDY FINDINGS ALCOHOL

- ABA CoLAP/Hazelden Betty Ford Foundation Study




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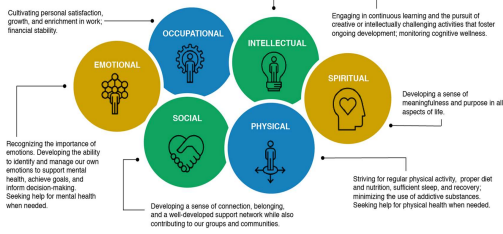
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## WHAT IS LAWYER "WELL-BEING"?

A continuous process in which lawyers strive for thriving in each dimension of their lives:




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## COLORADO TASK FORCE ON LAWYER WELL-BEING



The Colorado Task Force on Lawyer Well-Being first convened in September 2018 to promote greater well-being in the Colorado legal community and, in doing so, to help maintain public confidence in the profession.

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**SOME NATIONAL TASK FORCE  
RECOMMENDATIONS**

- Leaders should demonstrate a personal commitment to well-being
- Facilitate, destigmatize, and encourage help-seeking behaviors
  - Take steps to minimize the stigma of mental health and substance use disorders, which prevents lawyers from seeking help
- Foster collegiality and respectful engagement throughout the profession
  - Chronic incivility increases burnout and inflicts emotional and physiological damage

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**ADDITIONAL  
RESOURCES**

- 
- Office of Attorney Regulation Counsel
    - [coloradosupremecourt.com](http://coloradosupremecourt.com)
  - Colorado Lawyer Assistance Program
    - [coloradolap.org](http://coloradolap.org)
  - Colorado Attorney Mentoring Program
    - [coloradomentoring.org](http://coloradomentoring.org)
  - Colorado Bar Association:
    - [cobar.org](http://cobar.org)
  - CBA Ethics Hotline: 303-860-1115

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# **SECTION 2**

## **Stress Hardiness, Grit & Resiliency in the Legal Profession**



*Presented by*

**Amy Kingery, MBA, LCSW, LAC**  
Colorado Lawyer Assistance Program (COLAP)  
Denver, CO

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## RESILIENCY TO STRESS

### *Content Outline, Tips & Takeaways*

#### I. THE BASICS OF STRESS & RESILIENCY

- a. **What is Stress?:** Stress is the nervous system's response to a real or perceived threat. You can tell when your nervous system is activated by the way that you feel (see below for signs & symptoms). Whether the stimulus is an email, a headline, a comment made by opposing counsel, or an actual life-threatening situation, your brain will employ fight, flight, freeze, or faint strategies in an effort to cope.
- b. **Stressors & Stress:** Stress is the body's response to a perceived danger, stressor, or stimulus, is the event, situation, or thought that causes the nervous system to react. While we cannot control the "stressors," we can control our stress response through resiliency, grit, and stress hardiness techniques.
- c. **Eustress & Distress:** Research suggests that our interpretation of the stressor determines what kind of stress response our brain and body deploy.
  - i. **Eustress:** If we are excited about the challenge or situation, we perceive the stimulus and the stress as helpful, and therefore experience eustress. Physiologically the eustress response releases healing chemicals throughout the body.
  - ii. **Distress:** If the stimulus scares us, worries us, or we dread it and the stimulus is perceived as debilitating, our bodies deploy a distress reaction. The distress response was designed to be implemented on a short term basis, in response to life threatening situations. However, when stress is deployed on a long term basis, this response compromises our intelligence, problem solving abilities, physical health, and emotional intelligence.
  - iii. **Changing distress to eustress:** Practicing gratitude, appreciation, incorporating a sense of humor, and finding the silver lining in situations, are evidence-backed practices that help us turn our distress to eustress.
- d. **Predicting Distress:** Situations that create distress include chronic stressors we have no control over, situations where there is uncertainty and where there is an expectation of a negative outcome, the belief that we don't have the resources to cope, or feeling helpless, isolated and alone.
  - i. When we are in a state of chronic stress, all systems considered "non-essential for survival" will begin to conserve energy. Our digestive, reproductive, and immune systems are not considered crucial in a life-threatening emergency, so it is likely that the body will experience difficulties with digestion, reproduction (including sex drive), and immune response when stress is chronic.

- e. **Stress Becomes Trauma:** When we feel helpless or hopeless and find that we aren't "bouncing back" from difficulties, our stress creates neurological, physiological, and psychological changes we call trauma. Trauma is not an event; it is how the nervous system alters our thoughts, perceptions, personality, habits, and memories in an attempt to help us survive stressful events in the future. When our survival instincts kick-in, different parts of the brain can "hijack" one another and monopolize our energy and focus. For example, we might go into an "analysis paralysis" state of overthinking or worrying and exhibit an overreactive emotional state where we can't think logically or with compassion for others. Trauma impacts our relationships with others, influences our world view and behaviors, and increases the chance we will develop problematic substance use or mental issues, such as anxiety or depression.

## II. SIGNS & SYMPTOMS OF STRESS

- a. **Cognitive:** memory problems, poor judgement, seeing only the negative, anxious or racing thoughts, constant worrying
- b. **Emotional:** moodiness, irritability, agitation, feeling overwhelmed, sense of loneliness, depression/general unhappiness
- c. **Physical:** aches and pains, digestive issues, chest pain, frequent colds
- d. **Behavioral:** changes in eating or sleeping patterns, procrastination, use of drugs or alcohol, development of nervous habits such as pacing and nail biting
  - i. *Fight or flight* strategies: catastrophizing, feelings of abandonment, anger, resentment, leaving, or running away
  - ii. *Freeze or faint* strategies: apathy, depression, avoidance, overthinking, and dissociation or "zoning out"

## III. CONSIDERATIONS IN STRESS MITIGATION

- a. What symptoms do you experience when you are stressed? Assess your symptoms and recognize what you are feeling.
- b. Create a proactive plan for "how to take care of yourself when stressed," and make sure loved ones or trusted colleagues can provide help.
- c. Stress and emotions are contagious. Track your own emotional reactions and be aware of what you are responsible for (yourself), and recognize what may belong to someone else in terms of stress or emotional reaction. Increase awareness of how you are responding to stressors.
- d. What we see and hear become part of our own experience, so have discretion with what you expose yourself to when you can.
- e. Stress and emotions can be addictive; the more frequently you practice certain types of thoughts or emotional reactions to circumstance, the more the cells of your body crave those particular emotional states.

## IV. BUILDING RESILIENCY IN THE LEGAL PROFESSION

- a. **The Role of Relationships:** We are relational beings, and from Viktor Frankl's logotherapy to modern mindfulness and wellbeing experts such as Dan Siegel, it holds true that the strength of our relationships can enhance or detract from our ability

to “bounce back” in the face of stress and vicarious trauma. Watch Dr. Brené Brown’s “The Power of Empathy” at <https://www.youtube.com/watch?v=jz1g1SpD9Zo> and “Blame” at [https://www.youtube.com/watch?v=IL1JgIj3\\_fA](https://www.youtube.com/watch?v=IL1JgIj3_fA)

- b. **Routines, Rituals and Schedules:** During times of vast, unpredictable and sudden change our routines and schedules can either work for us or against us. Tune into how things such as movement, food, music, social media and the news may be impacting our moods, emotions and energy levels. If we are intentional, about managing our routines and schedules we can leverage these changes to our benefit. If left to run wild, change can also unintentionally derail us.
- c. **The Many Buckets of Wellness:** Wellness has many buckets including physical, spiritual, emotional, mental, communal, professional and familial. When we are in-tune with ourselves and understand how to fill each of our buckets for wellness, we grow more resilient and are more likely to bounce back should one of our buckets or “accounts” become unexpectedly drained, as described by Michael Hyatt in the book (Living Forward.)
- d. **Supporting Resiliency in the Workplace:** Workplaces which embrace a culture of trauma stewardship are better equipped to support a resilient team of attorneys, clients and legal staff for the long haul. World renowned Vicarious Trauma expert, Laura van Dernoot Lipsky coined the term, “Trauma Stewardship” to approach wellbeing and resiliency from a systemic and cultural level. TEDTalk: <https://www.youtube.com/watch?v=uOzDGrcvmus>
- e. **“Low Impact Debriefing:”** Maintain positive relationships at work. International Vicarious Trauma expert Françoise Mathieu coined this term for a research-backed strategy to vent, in a way that doesn’t “slime” your colleagues: <https://www.tendacademy.ca/wp-content/uploads/2019/07/Low-Impact-Debriefing-2019.pdf>
- f. **Mindfulness, Scent & Taste:** Taking a walk in nature, deep breathing, meditating, or simply breathing in the scent of citrus are excellent ways to ground yourself and renew your energy level. The scent of citrus reduces stress and anxiety, renews focus, enhances digestion, and helps brings us back from a state of “fight or flight,” and you can even eat an orange!
- g. **New to mindfulness or meditation?**
  - i. Watch this 3-minute Guide to Mindfulness from Happify: <https://www.youtube.com/watch?v=w6T02g5hnT4>
  - ii. Watch this 3-minute Guide to Meditation from Happify: <https://www.youtube.com/watch?v=o-kMJBWk9E0>
  - iii. Watch this 2-minute video on Negative Thinking: <https://www.youtube.com/watch?v=YXVwOOPu2n4>
  - iv. Try Deepak Chopra’s One Minute Meditation: <https://www.youtube.com/watch?v=JdG4z5kpD2s>

## V. QUICK SELF-CARE TIPS

- a. Time and attention management: Track your thoughts and focus throughout the day. Try to reduce negative, perseverating, obsessive, blaming, or angry thoughts

- and focus on being more humorous, positive, and creative.
- b. Create a ritual or routine to assist your mind and body in transitioning to and from work. This can include music, journaling, changing clothes, showering when you get home, exercise, etc.
  - c. Stand up and move more throughout the day.
  - d. When possible, do one task at a time rather than multitasking.
  - e. Listen to music that is uplifting or calming.
  - f. Repeat a calming mantra, prayer, or positive saying to yourself when distressed.
  - g. When you are upset and your stress is escalating, assess the situation to determine if the stressor is truly an immediate threat, or if it is your mind and body perceiving it as such. If it is the latter, remind yourself that you are safe and have the capability to choose a different response.
  - h. Identify what you cannot control and then choose to let it go.
  - i. Take breaks throughout the day, even if they are just momentary breaks to mindfully breathe, look around, and activate your senses.
  - j. Relax your jaw and release your tongue from the roof of your mouth.
  - k. Breathe deeply into your lower belly. Inhale for 5-10 seconds, pause, and exhale for 5-10 seconds.
  - l. Get at least 7-8 hours of sleep a night. Research shows lawyers are sleep deprived, and this negatively impacts our physical and mental health.
  - m. Garden, play with your pets or children, and engage in hobbies.

## VI. TED TALKS AND VIDEOS

- a. Brené Brown – Why Your Critics Aren't the Ones Who Count  
<https://www.youtube.com/watch?v=8-JXOnFOXQk>
- b. Amy Cuddy - Your Body Language Shapes Who You Are  
[https://www.ted.com/talks/amy\\_cuddy\\_your\\_body\\_language\\_may\\_shape\\_who\\_you\\_are](https://www.ted.com/talks/amy_cuddy_your_body_language_may_shape_who_you_are)
- c. Lisa Genova – What You Can Do To Prevent Alzheimer's  
[https://www.ted.com/talks/lisa\\_genova\\_what\\_you\\_can\\_do\\_to\\_prevent\\_alzheimer\\_s?language=en](https://www.ted.com/talks/lisa_genova_what_you_can_do_to_prevent_alzheimer_s?language=en)
- d. Alison Ledgerwood – Getting Stuck in the Negatives (and how to get unstuck)  
[https://www.ted.com/talks/alison\\_ledgerwood\\_a\\_simple\\_trick\\_to\\_improve\\_positive\\_thinking](https://www.ted.com/talks/alison_ledgerwood_a_simple_trick_to_improve_positive_thinking)
- e. Kelly McGonigal – How to Make Stress Your Friend  
[https://www.ted.com/talks/kelly\\_mcgonigal\\_how\\_to\\_make\\_stress\\_your\\_friend](https://www.ted.com/talks/kelly_mcgonigal_how_to_make_stress_your_friend)
- f. Alison Tan – The Abundance of Letting Go  
<https://www.youtube.com/watch?v=nxeWlrPoLeQ>

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# **SECTION 3**

## **Stark and Anti-Kickback Statute Updates – Final Stark and Safeharbor New Regulations**



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# Modernizing the Stark Law and Anti-Kickback Statute

*New Policies, Exceptions, and Safe Harbors*

Meghan Pound and Jennifer Sullivan  
Caplan and Earnest LLC



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## Today's Presentation

- Statutory Basis
- History and Purpose of the New Stark and AKS Regulations
- Highlights of New Stark Regulations
- Promoting Value Based Care - Stark Exceptions and AKS Safe Harbors
- Other New/Revised AKS Safe Harbors

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## Statutory Basis

- **Stark Law** - Prohibits referrals by a physician for DHS payable by Medicare if the physician or an immediate family member has a financial relationship with the DHS entity that does not meet a Stark exception.
  - Medicaid referrals covered by Colorado Law
    - Strict liability
  - Physicians - MDs, DOs, Chiropractors, Dentists, Optometrists 42

USC § 1395nn
- **AKS** - A criminal statute that prohibits the knowing and willful offer, solicitation, payment or receipt of any form of remuneration to induce or reward patient referrals or the purchase, lease, order or other arrangement for any services, goods, facilities or items payable by a Federal health care program.
  - Requires intent
  - Applies to broader range of transactions
    - Not limited to physician referrals
    - Not limited to designated health services

42 USC § 1320a-7b

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## History and Purpose

- **HHS Regulatory Sprint to Coordinated Care -2018**
  - Aimed to accelerate the transformation of the health care system with a focus on removing barriers to care coordination and value-based care created by health care laws and regulations
- **CMS Patients over Paperwork Initiative -2017**
  - Aimed to relieve unnecessary regulatory burdens including those that potentially impede the transition to value-based care, the coordination of care across health care settings and other efforts to enhance efficiency and improve the patient experience
- **Experience with the SRDP**
  - CMS has received thousands of self-disclosures regarding non-compliant arrangements posing little risk of program abuse

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## Highlights of New Stark Regulations

- Regulatory Relief - Clarifications and Policy Changes
  - *Declaration of Intent*
  - *The Big Three - Bright Line Rules*
    - Commercially Reasonable
    - Fair Market Value
    - Volume and Value of Referrals/Other Business Generated
  - *Other Revised Definitions and Concepts*
    - DHS
    - Isolated Transactions
    - Group Practice
    - Ownership/Investment Relationships - Exclusions
    - Set in Advance Requirements
    - Directed Referrals
  - *New Enforcement Policies*
    - Period of Disallowance
    - Writing and Signature Requirements
    - Reconciling Payment Discrepancies
    - AKS Compliance
- New/Revised Exceptions - StandAlone
  - Risk Sharing Arrangements
  - Limited Remuneration to a Physician
- Promoting Value-Based Care: Stark Exceptions with AKS Counterparts
  - EHR
  - Cybersecurity Technology and Services
  - Value-Based Arrangements

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## CMS Declaration of Intent

- “As we emphasized in the proposed rule, our intent in interpreting and implementing section 1877 of the Act has always been ‘to interpret the [referral and billing] prohibitions narrowly and the exceptions broadly, to the extent consistent with statutory language and intent,’ and we have not vacillated from this position . . . .”
- “As described in more detail in section II of this final rule, we are eliminating certain requirements in our regulatory exceptions that may be unnecessary and revising existing exceptions. We are also establishing new exceptions for non-abusive relationships . . . .”

85 Federal Register 77492, 77495 77496 (December 2, 2020)

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## The Big Three - Bright Line Rules

- The Building Blocks of Stark Compensation Exceptions
- Commercially Reasonable
- Fair Market Value
- Volume or Value Standards

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## Commercially Reasonable

- An element of many compensation exceptions (e.g., rental agreements, employment, FMV, isolated transactions)
- **New Definition:** Commercially reasonable means that the particular arrangement furthers a *legitimate business purpose* of the parties to the arrangement and is *sensible*, considering the characteristics of the parties, including their size, type, scope, and specialty. *An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties*
  - Profitability is not always unrelated to the determination of whether an arrangement is commercially reasonable
  - The test is not focused solely on compensation terms; however, the compensation terms are an integral part of the arrangement and impact its ability to accomplish the parties' goals
- Requirement of a legitimate purpose is not met if a violation of AKS or other state/federal law
- Variations in Wording - i.e., "arrangement would be commercially reasonable even if there were no referrals *between the parties*" - means DHS referrals not OBG between the parties
- Definition applies only for purposes of the Stark Law; not binding on OIG

42 CFR § 411.351; 85 Federal Register 77492, 77530 -77535 (December 2, 2020)

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## The Volume or Value Standards

- Many exceptions provide that compensation *may not be determined in any manner that takes into account the volume or value of the physician's referrals to the DHS entity or the volume or value of other business generated ("OBG")* by the referring physician (e.g., employment, FMV, rental arrangements, and personal services exceptions)
- CMS has established two new special rules
  - Compensation *to* a physician or immediate family member
  - Compensation *from* a physician or immediate family member

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## Volume or Value Standards - Compensation Paid to a Physician

- **New Rule:** Compensation from a DHS entity to a physician (or immediate family member) takes into account the volume or value of referrals or other business generated only if—
    - The formula used to calculate the physician's (or immediate family member's) compensation includes the physician's referrals to [or other business generated by the physician for] the entity as a *variable*, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that *positively correlates* with the number or value of the physician's referrals to the entity.
    - A positive correlation between two variables exists when one variable decreases as the other variable decreases, or one variable increases as the other variable increases
- 42 CFR § 411.354(d)(5)
- **CMS Guidance:**
    - Connection between productivity bonus paid to an employed physician for *personally performed services* and DHS furnished by the employer (*Tuomey case*) does not violate this rule.
    - Fixed salary paid to a physician may exceed FMV but will never violate the Volume or Value Standard. These are two separate criteria.
  - See, AHLA Connections *CMS Sprints to Modernize the Stark Law, Part 1* for detailed commentary on this topic

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## Volume or Value Standards - Compensation Paid by a Physician

- **New Rule:** Compensation paid by a physician (or immediate family member) to a DHS entity takes into account the volume or value of referrals [or other business generated by the physician] only if—
  - The formula used to calculate the entity's compensation includes the physician's referrals to [or other business generated by the physician for] the entity as a variable, resulting in an increase or decrease in the entity's compensation that *negatively correlates* with the number or value of the physician's referrals to the entity
  - A negative correlation between two variables exists when one variable increases as the other variable decreases, or when one variable decreases as the other variable increases

42 CFR § 411.354(d)(6).

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## The Volume or Value Standards

- **CMS Commentary:**
  - Some exceptions use variations of this terminology - e.g., takes into account referrals or OBG "between the parties" or "by the physician." CMS interprets the varying terminology to mean "*by the referring physician.*"

85 Federal Register 77492, 77536 (December 2, 2020)
  - Special rules do not apply to—
    - Definition of indirect compensation arrangements
    - Exceptions for medical staff incidental benefits, professional courtesy, community-wide health information systems, electronic prescribing items and services, EHR donations, and cybersecurity technology and services
  - As of the effective date, the special rules at 42 CFR § 411.354(d)(2) and (3) are no longer relevant; retained to assist parties and CMS in applying policies in effect when a particular arrangement existed

85 Federal Register 77492, 77544 (December 2, 2020)

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## Fair Market Value

- CMS Commentary: The *fair market value* requirement is *separate and distinct from the volume or value standards*. The volume or value standards do not merely serve as *limiting phrases* to modify the fair market value requirement

85 Federal Register 77492, 77552 (December 2, 2020)

- CMS finalized three separate definitions for FMV that apply to
  - equipment rentals
  - office space rentals
  - other arrangements
- Definitions of FMV are similar to the statutory definition but incorporate the concept of General Market Value

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## Fair Market Value

- **General Rule:**
  - FMV is the value in an arm's length transaction -
    - *Consistent with the general market value of the subject transaction*
- **Equipment Rental:**
  - FMV is the value in an arm's length transaction -
    - *Of rental property for general commercial purposes (not taking into account its intended use)*
    - *Consistent with the general market value of the subject transaction*
- **Office Space Rental:**
  - FMV is the value in an arm's length transaction -
    - *Of rental property for general commercial purposes (not taking into account its intended use)*
    - *Without adjustment to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee*
    - *Consistent with the general market value of the subject transaction*

42 CFR § 411.351

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## General Market Value

- **New Rules for Purchase of Assets**
  - General Market Value is the price that an asset would bring on the date of acquisition of the asset as the result of bona fide bargaining between a well-informed buyer and seller that are not otherwise in a position to generate business for each other.
- **New Rule for Compensation**
  - General Market Value is the compensation that would be paid at the time the parties enter into the service arrangement as the result of bona fide bargaining between well-informed parties that are not otherwise in a position to generate business for each other.
- **New Rule for Rental of Equipment or Office Space**
  - General Market Value is the price that rental property would bring at the time the parties enter into the rental arrangement as the result of bona fide bargaining between a well-informed lessor and lessee that are not otherwise in a position to generate business for each other.
- **CMS Commentary**
  - General Market Value is inconsistent with any consideration of other business or referrals between the parties.
  - FMV compensation for physicians is not necessarily dictated by surveys; no 75<sup>th</sup> percentile rule

42 CFR § 411.351; 85 Federal Register 77492, 77555-77557 (December 2, 2020)

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## Other Updated Definitions/Concepts

- Designated Health Services
- Isolated Transactions
- Group Practice
- Indirect Compensation Relationships

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## Designated Health Services

➤ For services furnished to *inpatients* by a hospital, a services is not a DHS payable by Medicare if the furnishing of the service does not increase the amount of Medicare's payment under any of the following PPS systems:

- Acute Care Hospital Inpatient
  - Inpatient Rehabilitation Facility
  - Inpatient Psychiatric Facility
- Long Term Care Hospital

42 CFR § 411.351

➤ Example: Specialist who did not admit the patient to PPS hospital orders an x-ray; the inpatient services are not "tainted" in this situation

85 Federal Register 77492, 77571-77572 (December 2, 2020)

➤ Exclusion does not apply to services provided in outpatient setting

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## Isolated Transactions

➤ **New wording** clarifies that an isolated transaction includes a one-time sale of a property or practice, or a single instance of forgiveness of an amount owed in settlement of a *bona fide* dispute

➤ **CMS Commentary:**

- A single payment for multiple or repeated services (such as payment for services previously provided is not an isolated transaction
- An isolated financial transaction that is an instance of forgiveness of an amount owed in settlement of a *bona fide* dispute is not part of the compensation arrangement giving rise to the *bona fide* dispute. Thus, the settlement does not retroactively bring the compensation into compliance with Stark

42 CFR § 411.351; 85 Federal Register 77492, 77575-77580 (December 2, 2020)

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## Indirect Compensation

- **Revised Definition:** Incorporates *concepts* of special rules on compensation (including value or volume standards) into the definition of indirect compensation
- Previously this analysis was deferred to the second step of the process - determining whether the indirect compensation exception applies
- This change is intended to streamline the analysis and reduce the number of indirect compensation arrangements that are subject to Stark requirements

42 CFR § 411.354(c)(2); 85 Federal Register 77492, 77544-77547 (December 2, 2020)

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## Group Practice Rules for Distribution of Overall Profits

- **Relevance:** Definition of Group Practice is critical to Physician Services and IOAS exceptions
  - Definition allows physician member of the group to be paid a share of overall profits of the group if the share is not determined in a manner that is directly related to the volume or value of DHS referrals
- **New Rule:** *Overall profits means the profits derived from all of the DHS payable by Medicare of any component of the group that consists of at least five physicians*
  - *If there are fewer than five physicians in the group, overall profits means the profits derived from all the designated health services of the group*
  - *The profits from all DHS must be aggregated before distribution*
  - *May not distribute profits from DHS on a service-by-service basis*
- Profits directly attributable to a physician's participant in a value-based enterprise may be distributed to the physician
- Delayed effective date: January 1, 2022

42 CFR § 411.352(i); 85 Federal Register 77492, 77561 (December 2, 2020)

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## Ownership/Investment Relationships

➤ New Exclusions:

- Titular ownership/investment that excludes the right to receive financial benefits (e.g., profit distributions, dividends, sales proceeds, return on investment)
- Qualified Employee Stock Ownership Plan (ESOP) Ownership 42

CFR § 411.354(b)(3)

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## Set in Advance Requirements - Amending Compensation Terms

➤ CMS Commentary:

- Although modifications of the compensation terms of an arrangement are permissible . . . such modifications may pose a risk of program or patient abuse, because the modifications could be made in a manner that takes into account the volume or value of a physician's referrals or other business generated by the physician
- In order to prevent program or patient abuse (including abuse of the 90-day 'grace period' for documenting an arrangement in writing), it is necessary to codify certain requirements, including a writing requirement, for modified compensation to meet the set-in advance requirement of various exceptions

85 Federal Register 77492, 77594 (December 2, 2020)

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## Set in Advance Requirement - Amending Compensation Terms

- **New Rule:** Establishes requirements for meeting set in advance requirements when amending compensation terms
  - Modified compensation must be determined before the furnishing of items or services for which the modified compensation is to be paid - no retroactive amendments
  - Modified compensation must be set forth in writing before the furnishing of items or services for which the modified compensation is to be paid
    - 90-day grace period for writing requirements at §411.354(e)(4) does not apply
    - No signature requirement under

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## Set in Advance Requirement - Amending Compensation Terms

- Compensation arrangement as modified must satisfy all the requirements of an applicable exception on the effective date of the modification
- Compensation may be modified at any time and any number of times during the course of arrangement
  - Amended compensation terms are not required to remain in place 1 year from the date of amendment

42 CFR §411.354(d)(1)(ii); 85 Federal Register 77492, 77593-77595

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## Directed Referrals

- **Prior Rule:** Allowed a physician's compensation to be conditioned on referrals if certain criteria satisfied
- **New Requirement:** Applies when any portion of the physician's compensation is conditioned on directed referrals
  - The existence and amount of the compensation arrangement cannot be contingent *on the number or value* of the physician's referrals to a particular provider, practitioner, or supplier
    - Example: Cannot condition a physician's annual salary increase on meeting a referral target (number or value)
  - BUT the physician may be required to refer a specified percentage or ratio of patients to a particular provider, practitioner, or supplier
    - Example: Can condition a physician's annual salary increase on referring a certain percentage of patients to a particular provider
  - Rule applies even when the compensation formula does not take into account the volume or value of the physician's referrals

42 CFR § 411.354(d)(4); 85 FR 77492, 77547-77551 (December 2, 2020)

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## New Enforcement Policies

- Period of Disallowance
- Reconciling Payment Discrepancies
- Writing/Signature Requirements
- AKS Compliance

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## Period of Disallowance

- **Rule Change:** CMS removed previous wording defining the period of disallowance because too prescriptive and impractical
- **Policy:** The period of disallowance begins on the date when a financial relationship fails to satisfy an exception and ends when the relationship ends or is brought into compliance
- A facts and circumstances test will determine whether a financial relationship has ended or has been brought into compliance.
- One way to end the period of disallowance is to recover any excess compensation paid and re-establish compliance with applicable exception

42 CFR § 411.353(c)(1); 85 Federal Register 77492, 77581 (December 2, 2020)

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## Reconciling Payment Discrepancies

- **New Rule:** An entity may submit a claim (or a bill and payment may be made to the entity) if:
  - Within 90 days following the expiration or termination of a compensation arrangement, the parties reconcile all discrepancies in payments under the arrangement such that, following the reconciliation, the entire amount of remuneration for items or services has been paid as required under the terms and conditions of the arrangement; and
  - Except for the payment discrepancies, the compensation arrangement must fully comply with an applicable exception
  - Changes previous policy requiring all payment discrepancies to be made and discovered *during the course of the arrangement*
- **Caveats:** Retroactively curing noncompliant compensation arrangements by recovering or repaying problematic compensation is still prohibited; failing to correct a known discrepancy in a timely manner can create a secondary financial relationship

42 CFR § 411.353(h); 85 Federal Register 77492, 77581-78587 (December 2, 2020)

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## Writing and Signature Requirements

- Signature requirements may be satisfied by electronic signature or any signature form that is valid under State or Federal law
- Any requirement for a compensation arrangement to be set forth in writing and signed by the parties is met *as long as the compensation arrangement otherwise meets all of the requirements of an applicable exception* (e.g., set in advance), and the arrangement is *memorialized in writing and signed within 90 days* of the date that writing/signature were required
- Not available for amendments to compensation terms

42 CFR § 411.354(e)(3) and (4); 85 Federal Register, 77492, 77590-77593 (December 2, 2020)

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## Distinguishing the AKS

- CMS revised many exceptions to remove requirements for compliance with the AKS and/or billing and collection laws - e.g., exceptions for non-monetary compensation, IOAS, temporary non-compliance, physician recruitment, etc.
- This requirement still applies to the Fair Market Value exception
- Compliance with a Stark exception does not establish compliance with the AKS; AKS remains a backstop for addressing arrangements with wrongful intent

85 Federal Register 77492, 77567-77569

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## New/Revised Exceptions - Standalone

- Limited Remuneration to a Physician  
42 CFR § 411.357(z)
- Risk Sharing Arrangements  
42 CFR § 411.357(n)
- Payments by Physicians  
42 CFR § 411.357(i)
- FMV Arrangements  
42 CFR § 411.357(l)
- Office Space Rentals  
42 CFR § 411.357(a)
- Physician Recruitment  
42 CFR § 411.357(e)
- Recruitment of NPPs  
42 CFR § 411.357(x)

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## Limited Remuneration to a Physician

- **New Exception:** Originated from CMS review of numerous non-abusive relationships through the SRDP process  
85 Federal Register 77492, 77623 (December 2, 2020)
- Limited to \$5000 aggregate per calendar year, adjusted for inflation
  - Aggregate amount includes all compensation in a calendar year for items and services provided in reliance on the exception
  - Aggregate amount does not apply to compensation to a physician if the items or services are protected under an exception in §411.355 (general exceptions for ownership/investment and compensation arrangements) or the arrangement fully complies with all the requirements of another §411.357 exception
- Items or services must be actually provided by the:
  - Physician or
  - Physician's employees, wholly-owned entity, or a locum tenens physician

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## Limited Remuneration to a Physician

- Compensation cannot take into account value or volume of referrals or OBG
- Compensation must be FMV
- Must be commercially reasonable
- Exclusions for percentage based and per click equipment/space leases
- If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement must satisfy the directed referral rule (which includes both writing and set in advance requirements)
- Can be used with other exceptions (e.g., personal services and FMV) and the 90-day rule for meeting writing and signature requirements:
  - Parties may rely on the exception for limited remuneration to protect an arrangement at its outset; once the requirements of another exception are satisfied, the parties may rely on the other exception to protect the arrangement
  - If relying on another exception that includes writing and signature requirements, parties have up to 90 days to sign and document the arrangement under 42 CFR §411.354(e)(4)

42 CFR §411.357(z); 85 Federal Register 77492, 77622-77630 (December 2, 2020)

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## New/Revised Exceptions with AKS Counterparts

- EHR
- Cybersecurity
- Value-based Arrangements

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## Electronic Health Records - Exception and Safe Harbor

- The EHR exception and safe harbor protect the donation of interoperable *software or information technology and training services* that are necessary and used predominantly for *certain electronic health record purposes*.
- CMS and OIG collaborated on rule changes:
  - Donations may include cybersecurity software and services necessary and used predominantly to “protect” electronic health records
  - Software must be interoperable at the time of the donation
  - Safe Harbor’s list of eligible donors now includes health plans, any individual or entity, other than a laboratory company, that provides services covered by a Federal health care program and submits claims for payment, directly or by reassignment (as previously specified) AND *certain entities with indirect responsibility for patient care, such as health systems or accountable care organizations*.

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## Electronic Health Records - Exception and Safe Harbor Cont.

- Recipient must make required 15% contribution before receiving the initial donation or a donation of replacement items and services
- Recipient is not required to make its contribution in advance of other donations and the recipient’s contribution for other donations may be paid at reasonable intervals
- The donor may not finance the physician’s payment or loan funds to finance the recipient’s contribution
- Replacement items or services may be donated
- No sunset (previous expiration date of December 31, 2021)
- Proposed prohibition on information-blocking was omitted.

42 CFR § 411.357 (w); 42 CFR § 1001.952(y)

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## Cybersecurity Technology and Services - Exception and Safe Harbor

- **New Exception and Safe Harbor:** Permit the donation of *cybersecurity technology and services* that are necessary and used predominantly to implement, maintain or re-establish cybersecurity, subject to certain conditions
  - Cybersecurity is the process of protecting information by preventing, detecting and responding to cyberattacks.
  - Cybersecurity technology may include *hardware, software and other types of information technology*
- Safe harbor does not limit the type of individual or entity donating or receiving cybersecurity technology or services
- Exception and safe harbor establish similar requirements - e.g., a written agreement and prohibitions on conditioning the donation on future referrals (or conditioning future referrals on a donation) or otherwise taking into account the volume or value of referrals or other business generated between the parties when making donation decisions.
- Potential overlap with EHR rules  
42 CFR §411.357(bb); 42 CFR § 1001.952(jj)

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## Value-Based Arrangements

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## Introductory Comments

- The value-based concepts and definitions are used consistently in several exceptions and safe harbors in CMS's and OIG's final rules.
- CMS's value-based definitions found at: 42 C.F.R. § 411.351; 85 Federal Register 77661-77662 (Dec. 2, 2020).
- OIG's value-based definitions found at: 42 C.F.R. § 1001.952(ee)(14); 85 Federal Register 77890-77891(Dec. 2, 2020).

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## Value-Based Enterprise (VBE)

- *CMS and OIG adopted the same definition for value-based enterprise (or VBE).*
- VBE means two or more VBE participants:
  - Collaborate achieve at least one value-based purpose;
  - That have an "accountable body or person" responsible for financial and operational oversight of the VBE; and
  - That have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s).

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## VBE Participant

- *OIG and CMS adopted slightly different, yet consistent, definitions for VBE participants.*
- **OIG:** *Value-based enterprise participant or VBE participant* means an individual or entity that engages in at least one value-based activity as part of a value-based enterprise, other than a patient acting in their capacity as a patient, are not VBE participants.
  - **OIG** modified this definition from the **OIG** proposed rule to clarify that patients, acting in their capacity as a patient, are not VBE participants.
- **CMS:** *VBE participant* means a person or entity that engages in at least one value-based activity as part of a value-based enterprise.

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## Value-Based Purpose

- *OIG and CMS adopted the same definition for value-based purpose.*
- Value-based purpose means any of the following:
  - Coordinating and managing the care of a target patient population;
  - Improving the quality of care for a target patient population;
  - Appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population; or
  - Transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

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## Coordination and Management of Care

- OIG provided a definition for coordinating and managing care. CMS did not.
- OIG defines coordinating and managing care as “the deliberate organization of patient care activities and sharing of information between two or more VBE participants, one or more VBE participants and the VBE, or VBE participants and patients, that is designed to achieve safe, more effective, or more efficient care to improve the health outcomes of the target patient population.”

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## Target Patient Population

- *OIG and CMS adopted the same definition for target patient population.*
- *Target patient population* means an identified patient population selected by the VBE or its VBE participants using legitimate and verifiable criteria that:
  - are set out in writing in advance of the commencement of the value-based arrangement; and
  - further the value-based enterprise’s value-based purpose(s).

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# Value-Based Activity

## OIG's Definition

- Value-based activity:
  - means any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise:
    - The provision of an item or service;
    - The taking of an action; or
    - The refraining from taking an action; and
  - does not include the making of a referral

## CMS's Definition

- Value-based activity:
  - means any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise:
    - The provision of an item or service;
    - The taking of an action; or
    - The refraining from taking an action.

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# Value-Based Arrangement

- *OIG's and CMS's definitions are the same.*
- Value-based arrangement means an arrangement for the provision of at least one value-based activity for a target patient population to which the only parties are: (a) the value-based enterprise and one or more of its VBE participants; or (b) VBE participants in the same value-based enterprise.

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## Value-Based Safe Harbors and Exceptions

The final regulations have separate requirements for value-based arrangements involving full financial risk, downside financial risk and qualifying arrangements without strict financial requirements. OIG and CMS finalized the exceptions and safe harbors granting increased flexibility in value-based arrangements as the level of financial risk increases.

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## Value-Based Exceptions and Safe Harbors

### CMS

#### *New Exceptions*

- Full financial risk- 42 C.F.R. §411.357(aa)(1); 85 Federal Register 77680-77681 (Dec. 2, 2020).
- Meaningful downside financial risk to the physician- 42 C.F.R. §411.357(aa)(2); 85 Federal Register 77681 (Dec. 2, 2020).
- Value-based arrangements-42 C.F.R. §411.357(aa)(3); 85 Federal Register 77681 (Dec. 2, 2020).

### OIG

#### *Value-based Safe Harbors*

- Full financial risk- 42 C.F.R. § 1001.952(gg); 85 Federal Register 77892 (Dec. 2, 2020)
- Substantial downside financial risk- 42 C.F.R. § 1001.952(ff); 85 Federal Register 77891-77892 (Dec. 2, 2020).
- Care coordination arrangements 42 C.F.R. § 1001.952(ee); 85 Federal Register 77889-77890 (Dec. 2, 2020).

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## Stark Value-Based Exceptions

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## Common Requirements of Value-Based Arrangements

➤ The final Stark exceptions share five common requirements:

- The remuneration is for or results from value-based activities undertaken by the recipient for patients in the target population.
- The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.
- The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangements.
- If the remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the referral requirement must be in writing and signed by the parties and not prohibit referrals elsewhere based on patient preference, insurance requirements, or physician judgment.
- Records of the methodology for determining and the actual amount of the remuneration paid under the value-based arrangement must be maintained for at least six years and made available to the Secretary upon request.

\* The value-based AKS safe harbors contain similar requirements.

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## CMS-Full Financial Risk Exception

- Remuneration paid under a value- based arrangement is allowed if the following conditions are met:
- The VBE is at full financial risk (or is contractually obligated to be at full financial risk within the 12 months following the commencement of the value- based arrangement) during the entire duration of the value-based arrangement; and
  - Complies with the common requirements of value-based arrangements.

“Full financial risk” means that the VBE is financially responsible on a prospective basis for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time.

“Prospective basis” means that the value-based enterprise has assumed financial responsibility for the cost of all patient care items and services covered by the applicable payor prior to providing patient care items and services to patients in the target patient population.

42 C.F.R. §411.357(aa)(1); 85 Federal Register 77680-77681 (Dec. 2, 2020).

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## CMS- Meaningful Downside Financial Risk to the Physician Exception

- Remuneration paid under a value-based arrangement is allowed under this exception if the following conditions are met:
- The physician is at meaningful downside financial risk for failure to achieve the value-based purpose(s) of the VBE during the entire duration of the value-based arrangement.
  - A description of the nature and extent of the physician's downside financial risk is set forth in writing.
  - The methodology used to determine the amount of remuneration is set in advance of the undertaking of value -based activities for which the remuneration is paid.
  - Complies with the common requirements of value-based arrangements.

Meaningful downside financial risk means that the physician is responsible to repay or forgo no less than 10 percent of the total value of the remuneration the physician receives under the value-based arrangement.

42 C.F.R. §411.357(aa)(2); 85 Federal Register 77681 (Dec. 2, 2020).

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## CMS-Value-Based Arrangements

- Remuneration paid under a value-based arrangement is allowed under this exception if the following conditions are met:
  - The arrangement is set forth in writing and signed by the parties. The writing includes a description of:
    - The value-based activities to be undertaken under the arrangement;
    - How the value-based activities are expected to further the value-based purpose(s) of the VBE;
    - The target patient population for the arrangement;
    - The type or nature of the remuneration;
    - The methodology used to determine the remuneration; and
    - The outcome measures against which the recipient of the remuneration is assessed, if any.

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## CMS-Value-Based Arrangements Cont.

- The outcome measures against which the recipient of the remuneration is assessed, if any, are objective measurable, and selected based on clinical evidence or credible medical support.
- Any changes to the outcome measures against which the recipient of the remuneration will be assessed are made prospectively and set forth in writing.
- The methodology used to determine the amount of the remuneration is set in advance of the undertaking of the value-based activities for which the remuneration is paid.
- The arrangement is commercially reasonable.
- No less frequently than annually, or at least once during the term of the arrangement if the arrangement has a duration of less than 1 year, the value-based enterprise or one or more of the party's monitor:
  - Whether the parties have furnished the value-based activities required under the arrangement;
  - Whether and how continuation of the value-based activities is expected to further the value-based purpose(s) of the value-based enterprise; and
  - Progress toward attainment of the outcome measure(s), if any, against which the recipient of <sup>54</sup> the remuneration is assessed.

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## CMS-Value-Based Arrangements Cont.

- If the monitoring indicates that a value-based activity is not expected to further the value-based purpose(s) of the value-based enterprise, the parties must terminate the ineffective value-based activity. Following completion of monitoring that identifies an ineffective value-based activity, the value-based activity is deemed to be reasonably designed to achieve at least one value-based purpose of the value-based enterprise—
  - For 30 consecutive calendar days after completion of the monitoring, if the parties terminate the arrangement; or
  - For 90 consecutive calendar days after completion of the monitoring, if the parties modify the arrangement to terminate the ineffective value-based activity.
- Complies with the common requirements of value-based arrangements

Outcome measure means a benchmark that quantifies: (a) improvement in or maintenance of the quality of patient care; or reductions in the costs to or reductions in growth in expenditures in payors while maintaining or improving the quality of patient care.

42 C.F.R. §411.357(aa)(3); 85 Federal Register 77681 (Dec. 2, 2020).

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## Anti-Kick Back Value-Based Safe Harbors

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## OIG Final Rule—Ineligible Entities

- The following entities are included on the ineligible entity lists in all of the value-based safe harbors:
  - Pharmaceutical manufacturers, distributors, and wholesalers (“pharmaceutical companies”);
  - Pharmacy Benefit Managers (PBMs);
  - Laboratory companies;
  - Pharmacies that primarily compound drugs or primarily dispense compounded drugs (“compounding pharmacies”);
  - Manufacturers of devices or medical supplies;
  - Entities or individuals that sell or rent DMEPOS, other than a pharmacy or a physician, provider, or other entity that primarily furnishes services, (“DMEPOS companies”); and
  - Medical device distributors or wholesalers that are not otherwise manufacturers of devices or medical supplies (e.g., PODs).

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## Safe Harbor for Value-Based Arrangements with Full Financial Risk

- Under this safe harbor, remuneration does not include the exchange of payments or anything of value between a VBE and VBE participant pursuant to a value-based arrangements if in addition to the requirements mentioned above:
  - The VBE (directly or through a VBE participant, other than a payor, acting on behalf of the VBE) has assumed through a written contract or a value-based arrangement (or has entered into a written contract or a value-based arrangement to assume in the next 1 year) full financial risk from a payor.
  - The value-based arrangement is set forth in writing, is signed by the parties, and specifies all material terms, including the value-based activities and the term.
  - The VBE participant (unless the VBE participant is a payor) does not claim payment in any form from the payor for items or services covered under the contract or value-based arrangement between the VBE and the payor.
  - The remuneration provided by, or shared among the VBE and VBE participant: is directly connected to one or more of the VBE’s value based purposes; does not include the offer or receipt of an ownership or investment interest in an entity or any distributions related to such ownership or investment interest in an entity or any distributions related to such ownership or investment interest; and is not exchanged or used for the purpose of marketing items or services furnished by the VBE or a VBE participant to patients or for patient recruitment activities.
  - The value-based arrangement must not induce parties to reduce or limit medically necessary items or services furnished to any patient.
  - The VBE or VBE participant offering the remuneration does not take into account the volume or value of referrals of patients who are not part of the target patient population or businesses not covered under the value-based arrangement as a condition of payment
  - The VBE will have a quality assurance program for services furnished to the target patient population that protects against underutilization and assess the quality of care furnished to the target patient population.

42 C.F.R. § 1001.952(gg); 85 Federal Register 77892 (Dec. 2, 2020)

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## Safe Harbor for Value-Based Arrangements with Substantial Downside Financial Risk

- Substantial downside risk means:
  - Financial risk equal to at least 30 percent of any loss, where losses and savings are calculated by comparing current expenditures for all items and services that are covered by the applicable payor and furnished to the target patient population to a bona fide benchmark designed to approximate the expected total cost of such care;
  - Financial risk equal to at least 20 percent of any loss, where:
    - Losses and savings are calculated by comparing current expenditures for all items and services furnished to the target patient population pursuant to a defined clinical episode of care that are covered by the applicable payor to a bona fide benchmark designed to approximate the expected total cost of such care for the defined clinical episode of care; and
    - The parties design the clinical episode of care to cover items and services collectively furnished in more than one care setting; or
  - The VBE receives from the payor a prospective, per-patient payment that is:
    - Designed to produce material savings; and
    - Paid on a monthly, quarterly, or annual basis for a predefined set of items and services furnished to the target patient population, designed to approximate the expected total cost of expenditures for the predefined set of items and services.

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## Safe Harbor for Value-Based Arrangements with Substantial Downside Financial Risk Cont.

- Under this safe harbor, remuneration does not include the exchange of payments or anything of value between a VBE and a VBE participant pursuant to a value-based arrangement if:
  - The VBE (directly or through a VBE participant, other than a payor, acting on the VBE's behalf) has assumed through a written contract or a value-based arrangement (or has entered into a written contract or a value-based arrangement to assume in the next 6 months) substantial downside financial risk from a payor for a period of at least 1 year.
  - The remuneration provided by or shared among the VBE and VBE participant is directly connected to one or more of the VBE's value-based purposes.
  - The value-based arrangement must be in writing, is signed by the parties, and specifies all material terms.
  - The VBE or the VBE offering the remuneration does not take into account the volume or value of or condition the remuneration on: referrals of patients who are not part of the target patient population or businesses not covered under the value-based arrangement.
  - The value-based arrangement cannot limit the VBE participant's ability to make decisions in the best interests of its patients, direct or restrict referrals to a particular provider, practitioner, or supplier if: (a) a patient expresses a preference for a different provider, practitioner or supplier; (b) the patient's payor determines the provider, practitioner or supplier; or (c) such direction or restriction is contrary to applicable law or induce the parties to reduce or limit medically necessary items or services furnished to any patient.

42 C.F.R. § 1001.952(ff); 85 Federal Register 77891-77892 (Dec. 2, 2020)

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## Safe Harbor for Care Coordination Arrangements to Improve Quality, Health Outcomes and Efficiency

- In order to qualify for this safe harbor:
  - The remuneration must be in kind; used predominately to engage in value based activities that are directly connected to the coordination and management of care for the target patient population and does not result in more than incidental benefits to persons outside of the target patient population; and is not exchanged or used (A) more than incidentally for the recipients billing or financial management services; or (B) for the purpose of marketing items or services furnished by the VBE or a VBE participant to patients or for patient recruitment activities.

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## Safe Harbor for Care Coordination Arrangements to Improve Quality, Health Outcomes and Efficiency Cont.

- In addition:
  - The value-based arrangement must be commercially reasonable.
  - The terms of the value-based arrangement are set forth in writing and signed by the parties in advance of or contemporaneously with the commencement of the arrangement.
  - The parties to the value-based arrangement establish one or more legitimate outcome or process measures that the parties reasonably anticipate will advance the coordination and management of care for the target patient population based on clinical evidence or credible medical or health science support.
  - The offeror of the remuneration does not take into account the volume or value of or condition the remuneration on: referrals of patients not covered under the value -based arrangements; or businesses not covered under the value-based arrangement.
  - The value-based arrangement may not limit the VBE participant's ability to make decisions in the best interests of its patients nor induce parties to furnish medically unnecessary care or reduce or limit medically necessary care.
  - All recipients must pay either 15 percent of the offeror's cost for the remuneration or the fair market value of the in-kind remuneration.
  - The exchange of remuneration by a limited technology participant and another VBE participant or the VBE must not be conditioned on any recipient's exclusive use or minimum purchase of any item or service manufactured, distributed, or sold by the limited technology participant.
  - The VBE must monitor the achievement of the value-based purposes and remediate or terminate the VBE within a certain period of time if it is unlikely to achieve the desired outcomes for further coordination and management of care or if there are material quality deficiencies.
  - The offeror does not and should not know that the remuneration is likely to be diverted, resold, or used by the recipient for an unlawful purpose.

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## Additional New AKS Safe Harbors

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## Patient Engagement and Support

- Must only be an in-kind item, good, or service (not cash or a cash equivalent) and it must have a direct connection to the coordination and management of care of the target patient population.
- Tool or support must be recommended by the patient's licensed health care professional and must either ensure patient safety or advance: (a) adherence to a treatment or drug regimen or a follow up care plan established by the patient's licensed health care professional; or (b) prevention or management of a disease or condition as directed by the patient's licensed health care professional
- The tool or support does not result in medically unnecessary or inappropriate items or services reimbursed in whole or part by federal health care programs; and
- The availability of the tool or support cannot be determined in a way that considers the type of insurance coverage for patient.

The limit is \$500.00 per patient per year in aggregate retail value (adjusted for inflations) the tool or support may not be used to market other reimbursable items or services for patient recruitment purposes.

42 C.F.R. §1001.952(hh); 85 Federal Register 77892-77893 (Dec. 2, 2020).

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## CMS-Sponsored Models

- Model parties must reasonably determine that the model arrangement will advance one or more goals of the model;
- The exchange of value does not induce model parties or other providers or suppliers to furnish medically unnecessary items or services, or reduce or limit medically necessary items or services furnished to any patient
- The model parties do not offer, pay, solicit, or receive remuneration in return for, or to induce or reward, any federal health care program referrals or other federal health care program business generated outside of the model;
- The model parties in advance of or contemporaneous with the commencement of the model arrangement set forth the terms of the model arrangement in a signed writing that specifies, at a minimum, the activities to be undertaken by the model parties and the nature of the remuneration to be exchanged under the arrangement; and
- The model parties satisfy such programmatic requirements as may be imposed by CMS in connection with the use of this safe harbor.

42 C.F.R. §1001.952 (ii); 85 Federal Register 77894-77895 (Dec. 2, 2020).

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## ACO Beneficiary Incentive Programs for Medicare Shared Savings Program

- OIG clarified that remuneration does not include an incentive payment made by an Accountable Care Organization to an assigned beneficiary under a beneficiary incentive program established under section 1899(m) of the Social Security Act, if the incentive payment is made in accordance with requirements found in that subsection.

42 C.F.R. 1001.952(kk); 85 Federal Register 77894 (Dec. 2, 2020).

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## Exception to the Beneficiary Inducements CMP for Telehealth Technologies for In-Home Dialysis Patients

- Revised 42 C.F.R. 1003.110 to allow for the provision of telehealth technologies by a provider of services, physician, or a renal dialysis facility to an individual with end-stage renal disease who is receiving home dialysis for which payment is being made if:
- The telehealth technologies are furnished to the individual by the provider of services, physician or the renal dialysis facility that is currently providing the in-home dialysis, telehealth services, or other end-stage renal disease care to the individual, or has been selected or contacted by the individual to schedule an appointment to provide services;
  - The telehealth technologies are not offered as part of any advertisement or solicitation; and
  - The telehealth technologies are provided for the purpose of furnishing telehealth services related to the individual's end-stage disease.

42 C.F.R. 1003.110: 85 Federal Register 77894 (Dec. 2, 2020).

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## Modification of Three Other Safe Harbors

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## Amendments to Personal Services and Management Contracts Safe Harbor

- Modified the existing safe harbor for personal services and management contracts to add flexibility with respect to part-time arrangements.
- Instead of requiring the aggregate compensation be determined in advance, the safe harbor now requires that the methodology for determining the compensation paid to the agent over the term of the agreement is set in advance.
- No longer required that for services provided on a periodic, sporadic or part-time basis, the agreement specifies the schedule of such intervals, their precise length, and the exact charge for such intervals.

42 C.F.R. § 1001.952(d); 85 Federal Register 77888 (Dec. 2, 2020)

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## Amendments to Safe Harbor for Warranties

- OIG expended the warranty safe harbor to protect warranties covering a bundle of one or more items and related services.
- This safe harbor is available to any type of entity and therefore, may be a way for manufacturers and supplies to offer value- based arrangements.

42 C.F.R. 1001.952(g); 85 Federal Register 77888 (Dec. 2, 2020).

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## Amendments to Safe Harbor for Local Transportation

- Transportation provided still may not involve air, luxury or ambulance-level transportation. However, OIG clarified in commentary that ride sharing services, or other taxi services can be used to provide free or discounted transportation.
- OIG defined established patient as a person who has selected and initiated contact to schedule an appointment with a provider or supplier or who previously attended an appointment with the provider supplier.
- The 2020 rule expanded the radius in which providers can provide free transportation from a 50- mile radius to a 75-mile radius in rural areas. Transportation can only be provided to patients within a 25-mile radius from the provider in urban areas.
- OIG did not make any substantive changes to provisions in this safe harbor related to shuttle services or the prohibition of publicly marketing or advertising the free or discounted transportation services.

42 C.F.R. 1001.952(bb); 85 Federal Register 77889 (Dec. 2, 2020)

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## Links to Final Rules

### **CMS Final Rule:**

<https://www.federalregister.gov/documents/2020/12/02/2020-26140/medicare-program-modernizing-and-clarifying-the-physician-self-referral-regulations>

### **OIG Final Rule:**

<https://www.federalregister.gov/documents/2020/12/02/2020-26072/medicare-and-state-health-care-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the>

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# **SECTION 4**

## **Artificial Intelligence in Healthcare – Strategies to Identify and Mitigate Privacy and Other Legal Risks**



*Presented by*

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# Artificial Intelligence in Healthcare – Strategies to Identify and Mitigate Privacy and Other Legal Risks

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and Security, DaVita*

*Chris Achatz, Partner, KO Law Firm*



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## Agenda



- Overview of Current Artificial Intelligence Technology
- Benefits and Consequences of Artificial Intelligence in Healthcare
- Overview of Data Privacy and Security Laws of Healthcare Artificial Intelligence
- Best Practices for Deploying Artificial Intelligence in a Healthcare Setting
  - Deploying AI in a Clinical Setting

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# Overview of Current Artificial Intelligence Technology

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## Artificial Intelligence in Health Care

- Artificial Intelligence [AI]– *Is the science and engineering of making intelligent machines, especially intelligent computer programs . . .*<sup>1</sup>
- Machine Learning [ML]– *A system that has the capacity to learn based on training on a specific task by tracking performance measures.*<sup>2</sup>
- AI/ML-based software, when intended to treat, diagnose, cure, mitigate, or prevent disease or other conditions, are medical devices under the Federal Food, Drug, and Cosmetic Act, and called “Software as a Medical Device” [SaMD]<sup>3</sup>

1) <http://imc.stanford.edu/articles/whatisai/whatisai.pdf>

2) US FDA Artificial Intelligence and Machine Learning Discussion Paper, available at: <https://www.fda.gov/media/122535/download>

3) US FDA Artificial Intelligence and Machine Learning Discussion Paper

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## Adoption of AI Has Been Slow but is Rapidly Accelerating

- Health care industry notoriously lags behind other industries in adoption of, and investment in, new technologies. AI is no different.<sup>1</sup>
  - Only 20% of health care organizations say they in the late stages of AI development.<sup>2</sup>
- But this is changing:<sup>3</sup>
  - 98% of health care organizations say that they either have an AI strategy in place (83%) or that they are developing one (15%).
  - 59% of senior health care executives anticipate that AI will deliver tangible cost savings within three years (90% increase since 2018)
  - “With so many health care organizations pressing forward with AI, those that take too long to act are at risk of being left behind.”
- Biggest drivers of investment in AI:<sup>4</sup>
  1. Improving health outcomes
  2. Improving patient experience
  3. Decreasing per capita cost of care
  4. Improving provider experience

1) International Data Corporation (IDC) White Paper, “AI in Healthcare: Early Stage with Steady March to Maturity; available at [https://www.intersystems.com/isc-resources/wp-content/uploads/sites/24/AI\\_in\\_Healthcare-IDC\\_report.pdf](https://www.intersystems.com/isc-resources/wp-content/uploads/sites/24/AI_in_Healthcare-IDC_report.pdf).

2) Third Annual Optum Survey on AI in Health Care; available at: <https://www.optum.com/content/dam/optum3/optum/en/resources/ebooks/3rd-annual-ai-survey.pdf>

3) Third Annual Optum Survey on AI in Health Care

4) Third Annual Optum Survey on AI in Health Care

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## Examples of AI Health Care Use Cases<sup>1</sup>

- Predictive analytics to identify at risk patients
- Reading images to assist with diagnosis
- Inferencing to improve data quality
- Robot assisted surgery
- Virtual nursing assistants
- Dosing error reduction/ dosing optimization
- Connected machines/interoperability
- Administrative workflow efficiency
- Security (e.g. cyber security, fraud detection)

1) Source: Brian Kalis, Matt Collier, and Richard Fu, Harvard Business Review, *10 Promising AI Applications in Health Care*, May 10, 2018; available at: <https://www.investkl.gov.my/assets/multimediaMS/file/10-Promising-AI-Applications-in-HealthCare.PDF>

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## Top 3 applications according to Optum survey:<sup>2</sup>

1. Monitoring data from IoT devices (e.g. wearable technology)
2. Accelerating research for new therapeutic or clinical discoveries
3. Assigning codes for acute diagnosis and reimbursement

1) Source: Brian Kalis, Matt Collier, and Richard Fu, Harvard Business Review, *10 Promising AI Applications in Health Care*, May 10, 2018; available at: <https://www.investkl.gov.my/assets/multimediaMS/file/10-Promising-AI-Applications-in-HealthCare.PDF>, International Data Corporation (IDC) White Paper, "AI in Healthcare; Early Stage with Steady March to Maturity; available at [https://www.intersystems.com/isc-resources/wp-content/uploads/sites/24/AI\\_in\\_Healthcare-IDC\\_report.pdf](https://www.intersystems.com/isc-resources/wp-content/uploads/sites/24/AI_in_Healthcare-IDC_report.pdf).

2) Third Annual Optum Survey on AI in Health Care.

3) IDC White Paper.

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## Top 3 applications according to IDC Survey:<sup>3</sup>

1. Inferencing to improve data quality
2. Reading images to assist with diagnosis
3. Early identification of hospital acquired infection

1) Source: Brian Kalis, Matt Collier, and Richard Fu, Harvard Business Review, *10 Promising AI Applications in Health Care*, May 10, 2018; available at: <https://www.investkl.gov.my/assets/multimediaMS/file/10-Promising-AI-Applications-in-HealthCare.PDF>, International Data Corporation (IDC) White Paper, "AI in Healthcare; Early Stage with Steady March to Maturity; available at [https://www.intersystems.com/isc-resources/wp-content/uploads/sites/24/AI\\_in\\_Healthcare-IDC\\_report.pdf](https://www.intersystems.com/isc-resources/wp-content/uploads/sites/24/AI_in_Healthcare-IDC_report.pdf).

2) Third Annual Optum Survey on AI in Health Care.

3) IDC White Paper.

## Examples of AI Health Care Use Cases

- Predictive analytics to identify at risk patients

- DaVita and Renalytix AI are launching a program aimed at earlier detection of at risk patients
  - KidneyIntelX generates a patient specific risk score utilizing a ML algorithm based on blood biomarkers and electronic health records
  - The program seeks to identify patients for earlier intervention.

*Almost 50% of people whose kidneys fail find out after its too late, and we are on a mission to change that*  
- Javier Rodriguez, CEO of DaVita

- DaVita also used AI/predictive analytics to identify peritoneal dialysis patients who are at higher risk of hospitalization events.
  - Predictions are built into work flows, allowing nurses and care teams to intervene when necessary to avoid hospitalizations and keep patients on their home modality of choice
  - Hospitalization often leads patients to leave peritoneal dialysis therapy

- 1) DaVita, RenalytixAI to launch program aimed at earlier kidney disease detection, available at: <https://www.healio.com/news/nephrology/20210106/davita-renalytixai-to-launch-program-aimed-at-earlier-kidney-disease-detection>
- 2) Innovation in Home Care Delivery Improves the Quality of Life for More Kidney patients, available at: <https://pressreleases.davita.com/2019-07-30-Innovation-in-Home-Care-Delivery-Improves-the-Quality-of-Life-for-More-Kidney-Patients?mobile=No>

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## Benefits and Consequences of Artificial Intelligence in Healthcare

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## Benefits of AI in Health Care<sup>1</sup>

1. Pushing the limits of Human Performance
2. Expanding Access to Medical Expertise (Democratization)
3. Automating repetitive tasks
4. Managing resources

1) Source: W. Nicholson Price II, [Brookings](https://www.brookings.edu/research/risks-and-remedies-for-artificial-intelligence-in-health-care/), *Risks and Remedies for Artificial Intelligence in Health Care*, Nov. 14, 2019, available at: <https://www.brookings.edu/research/risks-and-remedies-for-artificial-intelligence-in-health-care/>.

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## Benefits of AI in Health Care

1. Pushing the limits of Human Performance

*“The flashiest use of medical AI is to do things that human providers – even excellent ones, cannot yet do.”<sup>1</sup>*

Examples:

- DaVita/RenalytixAI
- Google Health’s DeepMind program can predict onset of Acute Kidney Injury 48 hours before doctor’s spot it.<sup>2</sup>

1) [Brookings](https://www.brookings.edu/research/risks-and-remedies-for-artificial-intelligence-in-health-care/), *Risks and Remedies for Artificial Intelligence in Health Care*,

2) [Google’s DeepMind says it’s AI tech can spot acute kidney disease 48 hours before doctor’s spot it](https://www.cnn.com/2019/07/31/google-deepmind-says-its-ai-sees-acute-kidney-disease-48-hours-early.html), July 31, 2019, available at: <https://www.cnn.com/2019/07/31/google-deepmind-says-its-ai-sees-acute-kidney-disease-48-hours-early.html>

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# Benefits of AI in Health Care

## 2. Expanding Access to Medical Expertise (Democratization)

- MIT/Harvard researchers teamed up with clinicians at Beth Israel Deaconess and Mass General Hospital to evaluate the effectiveness of automated evaluations of lymphnode tissue with patients with breast cancer versus results from pathologist.<sup>1</sup>
  - The automated diagnostic method was accurate 92% of the time;
  - Pathologists alone were accurate 96% of the time.
  - The combination of findings from the automated approach and pathologists' findings achieved an accuracy rate of 99.5%.
- Democratization occurs when healthcare organizations are able to use AI to supplement local expertise.

1) International Data Corporation (IDC) White Paper, "AI in Healthcare; Early Stage with Steady March to Maturity; available at [https://www.intersystems.com/isc-resources/wp-content/uploads/sites/24/AI\\_in\\_Healthcare-IDC\\_report.pdf](https://www.intersystems.com/isc-resources/wp-content/uploads/sites/24/AI_in_Healthcare-IDC_report.pdf).

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3. Automating repetitive tasks
4. Managing resources

1) Source: W. Nicholson Price II, [Brookings, Risks and Remedies for Artificial Intelligence in Health Care](https://www.brookings.edu/research/risks-and-remedies-for-artificial-intelligence-in-health-care/), Nov. 14, 2019, available at: <https://www.brookings.edu/research/risks-and-remedies-for-artificial-intelligence-in-health-care/>.

## Risks posed by the use of AI in Health Care<sup>1</sup>

1. Errors and mistakes
2. Privacy and Security (including ethical and reputational challenges)
3. Data accessibility and integrity
4. Bias and inequity
5. Human knowledge and impact on human expertise
6. Hesitancy and skepticism (Nirvana Falacy)

1) Source: W. Nicholson Price II, Brookings, *Risks and Remedies for Artificial Intelligence in Health Care*, Nov. 14, 2019, available at: <https://www.brookings.edu/research/risks-and-remedies-for-artificial-intelligence-in-health-care/>.

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## FDA AI/ML-based SaMD Action Plan<sup>1</sup>

1. Tailored regulatory framework for AI/ML-based SaMD
2. Good Machine Learning Process (GMLP)
3. Patient-centered approach incorporating transparency to users
4. Regulatory Science Methods Related to Algorithm Bias and Robustness
5. Real World Performance

*FDA's vision is that, with appropriately tailored total product lifecycle-based regulatory oversight, AI/ML-based SaMD will deliver safe and effective software functionality that improves the quality of care that patients receive.<sup>2</sup>*

1) US FDA Artificial Intelligence/Machine Learning-Based Software as a Medical Device Action Plan, January 2021, available at: <https://www.fda.gov/media/145022/download>  
2) US FDA Artificial Intelligence/Machine Learning-Based Software as a Medical Device Action Plan.

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## What Impact has COVID-19 Had on AI, and Vice Versa?

- 56% of health care senior executives say that their response to COVID-19 has led them to accelerate or expand their AI deployment<sup>1</sup>
- AI is being used to diagnose, treat, and prevent the spread of COVID-19
  - AI and ML used to detect disease in lung scans and improve treatment options<sup>2</sup>
  - AI and ML used to predict lengths of hospitalizations and probable outcomes of patients<sup>3</sup>
  - MIT Researchers use AI to find drugs that could be repurposed for COVID-19<sup>4</sup>
  - Use of robots and AI can reduce potential transmission by reducing human contact<sup>5</sup>
    - Thermal cameras deployed in place of one-to-one temperature screenings and integrated to visitor and employee records to facilitate contact tracing and follow ups
    - Camera systems can even be trained to detect unwell persons through identification of contactless vital signs indicative of COVID-19 including: temperature, sound, and gesture sensors to detect cough.

1) Third Annual Optum Survey on AI in Health Care; available at: <https://www.optum.com/content/dam/optum3/optum/en/resources/ebooks/3rd-annual-ai-survey.pdf>

2) Healthcare IT News, *MIT Researchers Use AI to Find Drugs That Could be Repurposed for COVID-19*, Feb. 15, 2021, available at: <https://www.healthcareitnews.com/news/mit-researchers-use-ai-find-drugs-could-be-repurposed-covid-19>

3) Healthcare IT News, *MIT Researchers Use AI to Find Drugs That Could be Repurposed for COVID-19*

4) Healthcare IT News, *MIT Researchers Use AI to Find Drugs That Could be Repurposed for COVID-19*

5) Healthcare IT News, *AI-Powered Solutions in Tackling COVID-19 and Beyond*, Dec. 14, 2020, available at: <https://www.healthcareitnews.com/news/apac/ai-powered-solutions-tackling-covid-19-and-beyond>

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## Overview of Data Privacy and Security Laws of Healthcare Artificial Intelligence

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## Overview of Data Privacy and Security Laws and Regulations of Healthcare Artificial Intelligence

- **Health Insurance Portability and Accountability Act (HIPAA):**
  - Regulates the data privacy and security requirements of protected health information (PHI).
  - Enforced by Health and Human Services (HHS).
- **Federal Trade Commission Act (FTCA):**
  - Prohibits deceptive and unfair practices affecting interstate commerce.
  - Enforced by the Federal Trade Commission (FTC).
- **State Data Privacy Laws:**
  - Regulates the collection, use, disclosure, and consumer rights in personal information.
  - Enforced by State Attorneys General (and, coming 2023, state privacy regulators—i.e., CPPA)
- **State Data Security Laws:**
  - Requires the implementation and maintenance of reasonable administrative, technical, and physical safeguards of personal information.
  - Enforced by State Attorneys General.
- **State Data Breach Notification Laws:**
  - Requires certain notification measures in the event of the unauthorized access or acquisition of personal information.
  - Enforced by State Attorneys General.

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## HIPAA – Applicability to AI Applications

- In 2016, HHS released Health App Guidance that may inform whether an AI application developer is a Business Associate (BA).
- Under the 2016 guidance, an AI application developer should consider:
  1. Is the developer's AI application independently selected by an individual?
  2. Does the individual control all decisions concerning whether to transmit the individual's data to a third party, for example, to the health plan in which the individual is a participant or to a health plan provider?
  3. Does the developer instead have no relationship with the third party health plan or provider (other than an interoperability relationship)?

1) Source: Health App Guidance - <https://hipaaqportal.hhs.gov/community-library/accounts/92/925889/Public/OCR-health-app-developer-scenarios-2-2016.pdf>

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## Example 1 – Is the App Developer a HIPAA BA?

**Scenario:** Consumer downloads a health app to her smartphone that is designed to help her manage a chronic condition. Health care provider and app developer have entered into an interoperability arrangement at the consumer's request that facilitates secure exchange of consumer information between the provider EHR and the app. The consumer populates information on the app and directs the app to transmit the information to the provider's EHR. The consumer is able to access test results from the provider through the app.

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## Example 1 – Is the App Developer a HIPAA BA?

**Scenario:** Consumer downloads a health app to her smartphone that is designed to help her manage a chronic condition. Health care provider and app developer have entered into an interoperability arrangement at the consumer's request that facilitates secure exchange of consumer information between the provider EHR and the app. The consumer populates information on the app and directs the app to transmit the information to the provider's EHR. The consumer is able to access test results from the provider through the app.

**HHS Guidance:** No. Developer is not creating, receiving, maintaining or transmitting protected health information (PHI) on behalf of a covered entity or another business associate. The interoperability arrangement alone does not create a BA relationship because the arrangement exists to facilitate access initiated by the consumer. The app developer is providing a service to the consumer, at the consumer's request and on her behalf. The app developer is transmitting data on behalf of the consumer to and from the provider; this activity does not create a BA relationship with the covered entity.

**Result:** App developer does not need to comply with HIPAA.

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## Example 2 – Is the App Developer a HIPAA BA?

**Scenario:** At direction of her provider, patient downloads a health app to her smart phone. Provider has contracted with app developer for patient management services, including remote patient health counseling, monitoring of patients' food and exercise, patient messaging, EHR integration and application interfaces. Information the patient inputs is automatically incorporated into provider EHR.

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## Example 2 – Is the App Developer a HIPAA BA?

**Scenario:** At direction of her provider, patient downloads a health app to her smart phone. Provider has contracted with app developer for patient management services, including remote patient health counseling, monitoring of patients' food and exercise, patient messaging, EHR integration and application interfaces. Information the patient inputs is automatically incorporated into provider EHR.

**HHS Guidance:** Yes, the developer is a business associate of the provider, because it is creating, receiving, maintaining and transmitting protected health information (PHI) on behalf of a covered entity. In this case, the provider contracts with the app developer for patient management services that involve creating, receiving, maintaining and transmitting PHI, and the app is a means for providing those services.

**Result:** App developer does need to comply with HIPAA as a BA.

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## HIPAA – Privacy Rule

- The Privacy Rule limits the use and disclosure of PHI by CE or BA where business relationship involve PHI.
- CE or BA may only use PHI with patient authorization for certain purposes, but need not obtain consent for treatment, payment, and health care operations.
- HIPAA sets a data privacy floor, not ceiling.
  - Some states have stronger protections with regard to certain health-related information (e.g., NY. Pub. Health Law § 2783 - HIV status; 740 Ill Comp Stat Ann 14/15 – Biometrics.).
  - Some states provide stronger protections for consumer personal information, which may include health-related information (e.g., CCPA, CDPA).

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## HIPAA – Privacy Rule

- Patient Notice and Consent/Authorization Issues in Healthcare AI
  - Initial Development of AI – Training healthcare AI
  - External Validation – Third-party validation of medical AI recommendations and predictions to validate algorithm quality.
  - Inference Generation – Inferential or derived data may itself be separate personal information.
- Minimum Necessary Standard Issues in Healthcare AI
  - AI processes generally require enormous amounts of data to be valuable.
  - Use and disclosure to only minimum necessary may hinder AI application development.
- Deidentification Issues in Healthcare AI
  - Deidentification can lead to data fragmentation and sub-optimal medical AI recommendations.
  - HIPAA Deidentification + AI = Deidentification Unicorn (e.g., Reidentification)?

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## HIPAA – Security Rule and Breach Rule

- Disclosure Issues in Healthcare AI
  - Vast AI processing operations may make PHI more vulnerable to interception or inadvertent access by third parties.
- Security Issues in Healthcare AI
  - Protecting the confidentiality, integrity, and availability of PHI requires that it not be altered in an unauthorized manner.

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FEDERAL TRADE COMMISSION  
PROTECTING AMERICA'S CONSUMERS

## FTC AI Framework

Using Artificial Intelligence and Algorithms

- April 8, 2020 – Director of FTC’s Bureau of Consumer Protection Guidance on the use of artificial intelligence and algorithms.
  - **Fair Credit Reporting Act** (1970) – Company that sells consumer information that is used for eligibility for credit, employment, insurance, housing, or similar benefits or transactions must provide adverse action notices and the right to correct inaccurate information.
  - **Equal Credit Opportunity Act** (1974) – Prohibits credit discrimination on the basis for race, color, religion, national origin, sex, marital status, age, or because a person receives public assistance. Note disparate impact (e.g., Zip codes as a proxy for race).
  - Guidance: **Big Data: A Tool for Inclusion or Exclusion** (2016) – Advised companies using big data analytics and machine learning to reduce the opportunity for bias.

1) Source: FTC AI Framework - <https://www.ftc.gov/news-events/blogs/business-blog/2020/04/using-artificial-intelligence-algorithms>

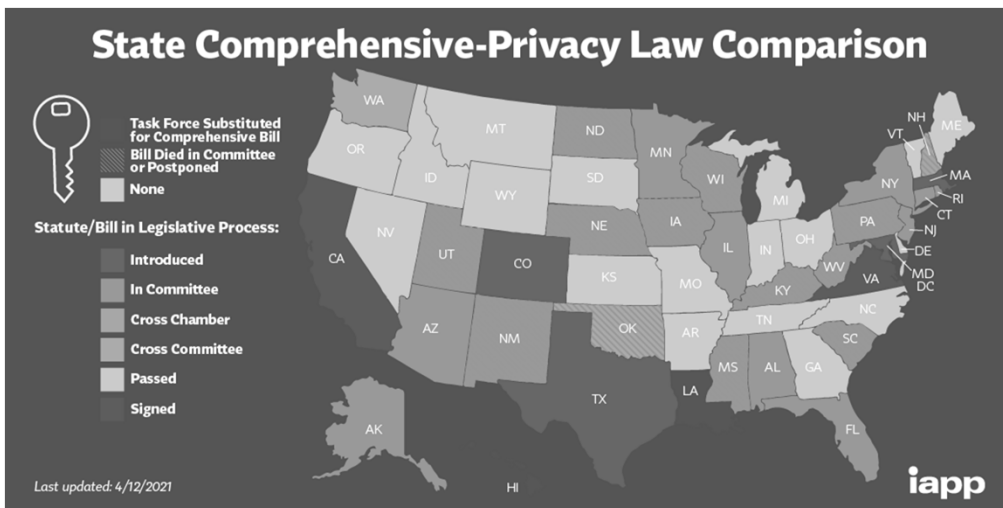
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# FTC AI Framework

Using Artificial Intelligence and Algorithms

1. **Transparency** – Companies that mislead consumers about the use of automated tools, such as AI chatbots that deceive consumers into believing they are communication with a live person could face FTC enforcement.
  - **CA Bolstering Online Transparency Act (BOT Act) (2019)** - Requires a platform company to disclose whether it is using a bot to communicate with the public.
2. **Fairness** – Consider disparate impact and bias created of algorithm. Both inputs and outputs evaluated.
3. **Empirically Sound** – Ensure AI models provide the maximum possible accuracy. Obtain outside validation of algorithms.
4. **Explain Decisions to Consumers** – Be prepared to disclose the key factors that impact the algorithm’s decision making and explain why the algorithm arrived at a particular result.

# State Data Privacy Laws



1) Source: IAPP US State Comprehensive Privacy Law Comparison - <https://iapp.org/resources/article/state-comparison-table/>

## Broad HIPAA Exception

EXAMPLE: Virginia – Consumer Data Protection Act (CDPA)

- CDPA's exemptions cover *all* types of information held by enumerated categories of exempt entities including "covered entities" and "business associates" subject to HIPAA.
- CDPA's exemptions cover identifiable private information for purposes of the federal policy for the protection of human subjects under 45 C.F.R. Part 46.
- CDPA's exemptions cover identifiable private information that is otherwise collected as part of human subjects research pursuant to the good clinical practice guidelines issued by The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.
- CDPA's exemptions cover the protection of human subjects under 21 C.F.R. Parts 6, 50, and 56, or personal data used or shared in research conducted in accordance with the requirements set forth in CDPA.
- CDPA's exemptions cover information derived from any of the health care-related information listed that is de-identified in accordance with HIPAA's requirements for de-identification.

1) Source: Virginia CDPA, § 59.1-572(B) and (C)

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## Consumer Rights – Right to opt out of profiling or automated decision making



EXAMPLE: Virginia – Consumer Data Protection Act (CDPA)

- CDPA provides consumers rights to opt out of the processing of the personal data for purposes of profiling in advancing decisions that produce legal or similarly significant effects concerning the consumer.

**"Profiling"** means any form of automated processing performed on personal data to evaluate, analyze, or predict personal aspects related to an identified or identifiable natural person's economic situation, health, personal preferences, interests, reliability, behavior, location, or movements.

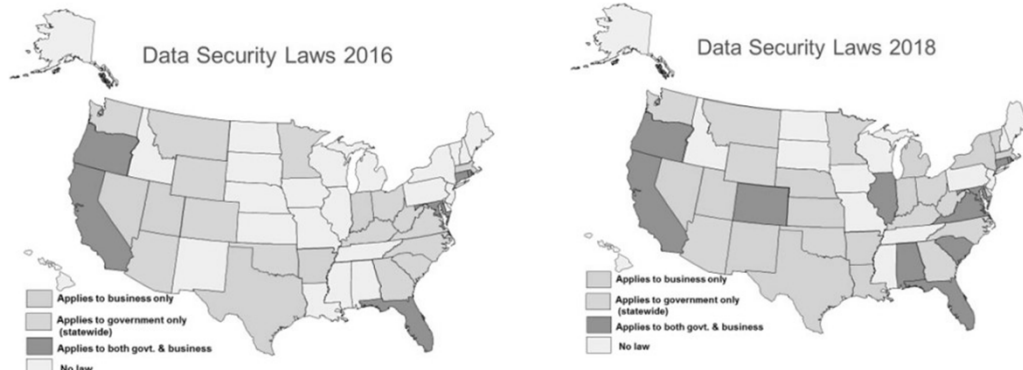
**"Decisions that produce legal or similarly significant effects concerning a consumer"** means a decision made by the controller that results in the provision or denial by the controller of financial and lending services, housing, insurance, education enrollment, criminal justice, employment opportunities, health care services, or access to basic necessities, such as food and water.

1) Source: Virginia CDPA, § 59.1-571 and 573(A)(5)

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## State Data Security Laws

- State data security laws require businesses that maintain personal information about a resident of that state to implement and maintain reasonable administrative, technical, and physical safeguards appropriate to the nature of the information and to protect the personal information from unauthorized access, destruction, use, modification, or disclosure.
- Generally does not include medical information or health insurance information, but could include biometric information.



1) Source: NCSL - <https://www.nass.org/sites/default/files/2019%20Summer/presentations/presentation-ncsl-summer19.pdf>

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## State Data Breach Notification Laws

- State data breach notification laws require businesses that maintain personal information about a resident of that state to notify individuals of security breaches (e.g., unauthorized access or acquisition) of personal information.
- Could include medical information and health insurance information, and may also include biometric information.



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## Best Practices for Deploying Artificial Intelligence in a Healthcare Setting

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### Start with a Holistic Approach

- Understand current operations and expected benefits from integrating AI solutions going forward
  - Justification for AI development, e.g. supplement existing resources or improve democratization/outcomes
  - Appetite for investment to implement and manage solutions going forward
- Centralized, enterprise-wide strategy
  - Cross-functional support from variety of operational and support teams
  - Ongoing risk assessment embedded into development and implementation

***When starting out, keep it simple and objective!***

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## Determine Operational Baseline

- Identify and evaluate existing technical operations
  - Current scope and volume of internal data sources
  - Modeling capabilities with limited additional investment
  - Budget allocations for investment in technology and management resources
- Analyze priority actions for program development
  - Supplement gaps in data without creating undue legal risks
    - Expanded collection or purchase of information
  - Development of internal models vs. reliance on 3<sup>rd</sup> party providers
  - Weigh balance of small, quick progress vs. one-in-a-million wins with increased risks

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## Set Centralized Management Structure

- Identify teams/stakeholders for regular involvement
  - Relevant teams may include: IT (operations & security), Privacy, Regulatory, Contracting, Compliance, Clinical Ops, Business Development, etc.
  - Delineate roles, responsibilities, reporting expectations, etc.
- Funnel strategic planning and ongoing operations through centralized function
  - Track proposals, use cases, development statuses, and relevant sponsors
  - Assess and advise on benefits, costs, and liability
  - Provide transparency to stakeholders and executives

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## Identify & Mitigate Potential Risks

- Identify potential risks that apply to AI program generally
  - Regulated industries, dynamic US state laws, and international regulations
  - Increased scrutiny for sale of information
  - Implementation of adequate security safeguards
- Continue risk assessments with model development, implementation, and reliance on results
  - Bias or inequity in data, both input and output
  - Uses of results that may increase other legal or clinical risks

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## Stay Agile!

- Dynamism inherent in health care and AI requires flexibility
  - Changing legal landscape at various regulatory levels
  - Limitations to efficacy and accuracy of AI models
  - Evolving clinical and commercial priorities
- Concurrent investment in program management AND technology
  - Models reliant on the teams developing and overseeing models and systems
  - Subject-matter experts critical to balance among AI program growth, clinical outcomes, and risk mitigation

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# SECTION 5

## **Report from Inside the Beltway: What's Going on (or Not)?**

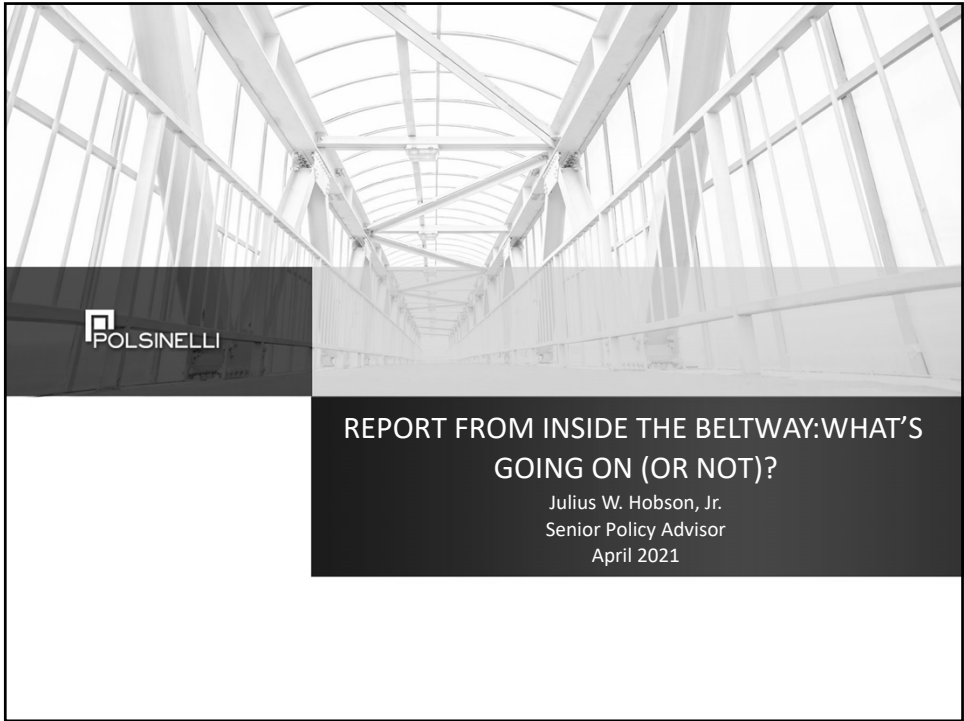


*Presented by*

**Julius W. Hobson, Jr.**  
Senior Policy Advisor  
Polsinelli PC  
Washington, DC

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## U.S. HOUSE OF REPRESENTATIVES 2020 ELECTION

### **116<sup>th</sup> Congress**

- Democrats: 233
- Republicans: 197
- Libertarian: 1
- Vacancies: 4

### **117<sup>th</sup> Congress**

- Democrats: 222 (-11) election results
- Today: 218
  - -3 Rep. Cedric Richmond [LA]; Marcia Fudge [OH]; & Deb Haaland [NM]
- Republicans: 212
- 5 Vacancies

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## UNITED STATES SENATE 2020 ELECTION

### **116<sup>th</sup> Congress**

#### **A:**

- 53 Republicans
- 47 Democrats

#### **B: Lame Duck**

- 52 Republicans
- 48 Democrats
  - Mark Kelly [AZ]

### **117<sup>th</sup> Congress**

- 50 Democrats
- 50 Republicans
- Vice President Harris makes Democrats the Majority
- Power Sharing Agreement
- Senators Joe Manchin [D-WV], Kyrsten Sinema [D-AZ] & the Filibuster

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## 2021 CONGRESSIONAL AGENDA

### Democrats Control Senate (50-50)

- Confirmation of Biden Cabinet Nominees
  - HHS
    - FDA (No nominee yet)
    - CMS (Chiquita Brooks-LaSure Nomination Status)
  - DoD
  - OMB (No Director)
- Further COVID-19 Stimulus
- Voting Rights Act Bill
- National Defense Authorization Act
- Insurrection Investigation
- Congressional Review Act
  - Repeal Trump Regulations
- Filibuster Reform
- Immigration Reform
- Minimum Wage Increase
  - \$15/\$11 per hour
- Tax Legislation
- FY 2022 Budget
  - Reconciliation
- Infrastructure Reform
- Gun Violence
- Affordable Care Act Reforms
- Other Health Care Issues
  - Drug Prices
  - Telehealth

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## AMERICAN RESCUE PLAN ACT OF 2021

[P. L. 117-2]

### Budget Resolution/Reconciliation Process

- **Health Policy Provisions**
  - Medicaid Coverage Expansion
  - DSH Fund
  - Medicaid Drug Rebates: In 2024 the law ends the cap on rebate that drug companies provide to Medicaid, which is currently limited to 100% of the average manufacturer price
  - COBRA: 100% subsidies
  - Defense Production Act: \$10 billion to purchase, produce & distribute medical supplies & equipment, including tests, face masks, PPE, and drugs and vaccines to treat and prevent COVID-19
  - Veterans Affairs funding
  - \$7.17 billion to cover purchase of broadband and service and devices by schools and libraries for use by students, staff, and patrons at other locations
  - Cybersecurity and IT
  - State and local assistance

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## AMERICAN RESCUE PLAN ACT OF 2021 [P. L. 117-2]

### **HHS Funding**

- 47.8 billion for testing and tracing activities
- \$8.5 billion for CDC vaccine activities
- \$7.66 billion to expand public health workforce
- \$7.6 billion for community health centers
- \$6.09 billion for tribal health programs
- \$3 billion for block grant programs for mental health & substance abuse
- \$800 million for health workforce
- \$750 million for CDC global health activities
- \$500 million for FDA to continue evaluating vaccines & therapeutics
- \$500 million for CDC data modernization & forecasting

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## THE WHITE HOUSE



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## BIDEN ADMINISTRATION AGENDA

- President's FY 2022 Budget proposal
- COVID-19 Management
  - Defense Production Act
  - Vaccine Distribution
- Further COVID-19 Stimulus
- Regulatory Review
  - Identify Trump Regulations: Repeal/Amend
- Reversing Trump Era Policies
  - Executive Order 13957, Creating Schedule F in the Excepted Service
- Trump Executive Orders Repealed
- Budget Review
- Unemployment
- Economy
- Environment
- Foreign Policy Review
  - China
- National Defense Review
- Health Care
  - ACA Fixes
  - Medicaid Expansion

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## BIDEN INFRASTRUCTURE PROPOSAL

- Fund traditional infrastructure: roads, highways, bridges, mass transit, etc.
- Biden redefined infrastructure to include:
  - Replace 100% of the nation's lead pipes and service lines
  - Upgrade & modernize America's drinking water, wastewater, and storm water systems and support clean water infrastructure across rural America
  - Build high-speed broadband infrastructure to reach 100% coverage
  - Build a more resilient electric transmission system
- Raising wages and benefits for essential home care workers

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## BIDEN REVENUE PROPOSALS

- Raise corporate tax rate to 28%, up from 21%
- Discourage offshoring by U.S. multinational corporations
- Prevent U.S. corporations from potentially escaping U.S. tax by inverting and switching their headquarters to foreign countries
- Prevent U.S. corporations from inverting or claiming tax havens as their residence
- Deny companies expense deductions for offshoring jobs and credit expenses for onshoring
- Eliminate a loophole for intellectual property that encourages offshoring jobs and invest in effective R&D incentives
- Enact a minimum tax on large corporations' book income
- Eliminate tax preferences for fossil fuels and make sure polluting industries pay for environmental clean up
- Ramping up enforcement against corporations

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## BIDEN FY 2022 DISCRETIONARY BUDGET PROPOSAL: HEALTH CARE

- Health & Human Services: \$133.7 billion [+\$25.1 billion/+23.1%]
- NIH: +\$9 billion
  - Establish Advanced Research Projects Agency for Health (ARPA-H) to continue support for research that enhances health: \$6.5 billion
- Centers for Disease Control & Prevention: \$8.7 billion [+\$1.6 billion]
- Doubles funding for the Community Mental Health Services Block Grant
- Promotes health equity by addressing racial disparities
- Addresses public health epidemic of gun violence
- Expand access to Family Planning Healthcare Services: \$340 million [+\$340 million/+18.7%]
- Rural health care access and expands the pipeline of rural healthcare providers

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## THE AMERICAN FAMILIES PLAN: HEALTH PROVISIONS

- \$1.8 trillion
- Expanding educational programs for nursing, allied health and skilled health care workers
- Investments in maternal health
- Plan doesn't directly address health-care policies but President has a plan to:
  - Lower drug costs by letting Medicare negotiate prices
  - Create a public health-care option
  - Lower the Medicare eligibility age to 60
  - Close the Medicaid "coverage gap" in states that didn't expand the program

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## THE AMERICAN FAMILIES PLAN: REVENUE PROVISIONS

- Extend expanded ACA premiums tax credits in the American Rescue Plan
- Extend Child Tax Credit increases in the American Rescue Plan through 2025 and make the Child Tax Credit permanently fully refundable
- Permanently increase tax credits to support families with child care needs
- Make the Earned Income Tax Credit expansion for childless workers permanent
- Give IRS authority to regulate paid tax preparers
- Revitalize enforcement to make the wealthy pay what they owe
- Increase the top tax rate on the wealthiest Americans to 39.6%
- End capital income tax breaks and other loopholes for the very top

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## JUDICIAL BRANCH



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## KEY CASES

- Affordable Care Act
- U.S. Census count of undocumented individuals
- Religious Freedom
- Medicaid Work Rules [case terminated]
- Federal Housing Financing Agency independence
- Trump's Border Wall Funding
- 340B Ruling: U.S. District Court Southern District of Indiana, Indianapolis Division [*Eli Lilly and Company, et al. v. Norris Cochran, et al.*]

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## FEDERAL RESERVE BOARD



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## FEDERAL RESERVE BOARD

- Interest Rates
- COVID-19 Activities
  - State and local government facility
  - Treasuries' Purchases
  - Main Street Lending Program
- Inflation issue
- Other Economic Stimulus Activities

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## REMAINING NON COVID-19 2020 HEALTH CARE ISSUES

- Prescription Drug Prices
  - Importation from Canada
  - Medicare Part D drug prices
- Affordable Care Act
- Public Option
- Medicare for All
- Health Care Access
- Oversight: HHS, Medicare and Medicaid
- Opioid Crisis
- Pharmacy Benefit Managers (U.S. Supreme Court)
- Gun Violence
- Health Care Workforce Issues
- Price transparency for hospitals (U.S. Court of Appeals for the District of Columbia)
- Immigration
- Vaping

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## IMPORTANT BUDGETARY ISSUES

- Sequestration
  - Sequestration moratorium expired March 31, 2021
  - Across-the-board budget reductions prevented
  - \$36 billion from Medicare
  - Social Security & low-income programs exempt from sequester
  - P. L. 117-7 extended temporary suspension until December 31, 2021
- Social Security Trust Fund
  - Originally projected to run out of funds in 2034
  - CBO now projects zero (0) balance by 2026
  - Social Security can not be handled through budget reconciliation
  - Primary cause: Pandemic unemployment
- Medicare HI Trust Fund
  - CBO projects zero (0) balance by 2026
  - Primary cause for earlier imbalance: Pandemic unemployment
- Debt Limit
  - Bipartisan Act of 2019 suspended the debt limit until July 31, 2021
  - If not suspended or raised, result is Federal government shutdown
  - \$1.7 trillion deficit mid-way through FY 2021
  - Senate Republicans

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## BUDGET RECONCILIATION PROCESS

- A procedure for changing existing revenue and spending laws to bring projected total federal revenues and spending within the parameters established in a budget resolution
- Reconciliation begins with directives in the budget resolution instructing specific committees to report legislation to respective Budget Committees
- House floor procedure—regular order
- Senate floor procedure—20 hours of debate on reconciliation bill [no filibuster/majority present an voting to pass]
  - 10 hours debate on reconciliation conference report—no amendments

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## OTHER ISSUES

- Infrastructure Reform
- European Union/NATO
- Iran
- Syria/Iraq/Somalia
- Afghanistan withdrawal
- China
- Saudi Arabia
- Trade
  - China
  - Argentina/Brazil steel tariffs
  - Canada aluminum tariffs
  - Rise in farm bankruptcies (up 20% in 2019/farm income decline)
- Russian Hack Problem
- Immigration
- Environmental Policy
- North & South Korea
- Energy policy
  - Coal
  - Oil & Gas drilling
  - Ethanol in gasoline
- Other National Intelligence/Security Issues
- **Unknown**

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## Question and Answers



Confidential - Not for Distribution

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## JULIUS W. HOBSON, JR. BIO

**Julius W. Hobson, Jr.** is Senior Policy Advisor, Polsinelli, where he concentrates on assisting clients with legislative and regulatory advocacy concerning health care, appropriations, budget, taxes, financial services, and various other public policy issues. With more than 49 years' experience working with the U.S. Congress and the Federal Executive Branch, he has served as Director, Division of Congressional Affairs, American Medical Association (AMA) where he managed the AMA's interaction with the Congress. Mr. Hobson previously served on the staff of Senator Charles Robb [D-VA] and the Committee on the Budget. While working in the Senate, he was responsible for appropriations, budget, financial services, taxes, and other economic issues. He previously served in the Executive Office of the District of Columbia Mayor where he was responsible for coordinating the city's relations with the Congress and the Federal Executive Branch. Mr. Hobson served in the U.S. House of Representatives as a subcommittee Staff Director and as Chief of Staff to a Member of the House. While serving in the House in 1985, Mr. Hobson was the principal staff person responsible for preparing the Congressional Black Caucus alternative budget. He also handled Congressional and Federal Affairs for Howard University. Mr. Hobson served a four-year term as an elected member of the D.C. Board of Education, during which he served a term as Vice President. He is currently Adjunct Professor, Graduate School of Political Management, The George Washington University, where he has taught the graduate course on lobbying since 1994 and also teaches Legislative Writing and Research. Mr. Hobson previously taught Advanced Strategy Lobbying, Fundamentals of Political Management, and Electoral and Legislative Processes. He is a graduate of Howard University (BA, History) and The George Washington University (MA, Legislative Affairs).

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# **SECTION 6**

## **State of the Healthcare Industry: Impact on Your Practice**



*Presented by*

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American Health Lawyers Association  
Washington, DC

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# State of the Healthcare Industry: Impacts on Your Practice

2021 Colorado State Bar Association,  
Health Care Law Symposium  
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# State of the Healthcare Industry: Impacts on Your Practice



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## AGENDA

### Impacting Your Practice

- Patient Demographics
- Who's Providing the Care
- Data, Data, Data
- Artificial Intelligence
- Consultant Competition
- Administrative Advocacy
- COVID

### Questions

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## CHANGING PATIENT DEMOGRAPHICS

- Increasing number of baby boomers reaching retirement.
- US Population that is foreign born will increase from 15% to 19% by 2060.
- Data empowers patients.
- Technology improves access.
- Millennials are better educated than prior generations.
- Social Determinants of Health / DEI
- [AHLA - Social Inequities as Enterprise Risks for Health Care Organizations](#)

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## WHO'S PROVIDING THE CARE

- Doctor Shortage.
- Technology and innovation matter.
- More care delivered at home.
- Primary care not provided by MDs.
- Diverse Workforce
- [AHLA - The Importance of Diversity in the Health Care Workforce](#)
- [AHLA - Technology and AI Liability](#)
- [AHLA - Non-physician practitioners](#)



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## DATA, DATA, DATA

- Data collection and use increasing.
- Data improves diagnostics.
- Breach and protection issues remain.
- [AHLA - More Data Please](#)
- [AHLA - Artificial Intelligence and Health Law](#)



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## ARTIFICIAL INTELLIGENCE

- Technology drives innovation.
- Telemedicine/Virtual Health.
- Speed and efficiency.
- Robots are not the lawyers of the future.
- [AHLA - Artificial Intelligence and Health Law](#)
- [AHLA - The Future Looks Bright for Telehealth...Mostly](#)



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## CONSULTANTS VS. LAWYERS

Generally, a non-lawyer can't:

- Provide legal advice to another
- Select legal documents on behalf of another
- Draft legal documents on behalf of another
- Interpret the law as it may apply to another
- Represent another person in any legal matter
- Prepare another person's case for trial



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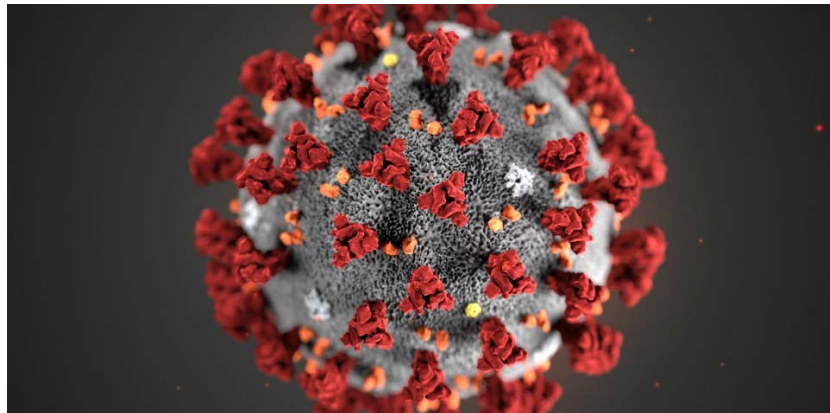
## ADMINISTRATIVE ADVOCACY

- What is Administrative Advocacy?
- AA should be a part of your practice.
- [Administrative Advocacy](#)



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# COVID |

[AHLA - Coronavirus Pandemic Hub](#)

[AHLA - The COVID-19 Vaccine and Health Care Employers](#)

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## **We Are AHLA**

### **Our Vision**

To lead health law to excellence through education, information, and dialogue.

### **Our Mission**

To provide a collegial forum for interaction and information exchange to enable its members to serve their clients more effectively; to produce the highest quality, nonpartisan, educational programs, products, and services concerning health law issues; and to serve as a public resource on selected health care legal issues.

### **Diversity and Inclusion**

In principle and in practice, the American Health Law Association values and seeks to advance and promote diverse and inclusive participation within the Association regardless of gender, race, ethnicity, religion, age, sexual orientation, gender identity and expression, national origin, or disability. Guided by these values, the Association strongly encourages and embraces participation of diverse individuals as it leads health law to excellence through education, information, and dialogue.

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## Membership Levels / Dues Benefits

	Full	Enhanced	Premium
<b>Benefits:</b>	<b>\$269</b>	<b>\$369</b>	<b>\$499</b>
AHLA Communities discussion groups	✓	✓	✓
Health Law Connections monthly magazine (digital and print)	✓	✓	✓
Journal of Health and Life Sciences Law (digital)	✓	✓	✓
Substantive health law eNewsletter subscriptions – Health Law Daily – Health Law Weekly – Newsstand on State Health Law Issues	✓	✓	✓
Practice Group(s) of your choice with automatic enrollment in associated Affinity Group(s)	1 Practice Group	2 Practice Groups	All Access Pass (Choose any or all Practice Groups)
Enrollment in ALL Task Forces	✓	✓	✓
Discounts on Live Webinars*	Member Discount: (\$50 savings)	One Free (Member Discount thereafter)	All Access Pass (Attend any or all Live Webinars FREE)

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	Full	Enhanced	Premium
Discounts on in-person and virtual programs	Member Discount (\$175 savings)	Additional Discount (\$225 total savings)	Deeper Discount (\$275 total savings)
FREE subscription to the <i>Health Law Archive</i> upon joining with discounted renewals or complimentary access in subsequent years	Member Discount (\$370 total savings)	Additional Discount (\$400 total savings)	All Access Pass (FREE)
Treatises and other publications, on-demand products (recorded webinars, ePrograms, etc.), and other products	Member Discount	Member Discount	Member Discount

\*Benefit refers to live webinars only and does not include on-demand products (recorded webinars, ePrograms, etc.).

Note: Receive \$100 off your Full or Enhanced membership when you are an academician, in-house counsel, paralegal, solo practitioner or work in the public sector (non-profit legal service or legal advocacy organization; federal, state or local government work setting; or public health organization or agency).

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## JOIN AHLA

Leading health law to excellence through education, information, and dialogue, the American Health Law Association (AHLA) is the nation's largest, nonpartisan, 501(c)(3) educational organization devoted to legal issues in the health care field with nearly 14,000 members.

[www.americanhealthlaw.org/join](http://www.americanhealthlaw.org/join)

### Save \$60 on membership dues

*valid through May 1, 2021 only*

Promo Code: **SAVE60**

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Learn more at: [americanhealthlaw.org/healthlawweek2021](http://americanhealthlaw.org/healthlawweek2021)



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Save The Date

Learn.  
Network.  
Connect

June 28-30, 2021

2021 Annual Meeting

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## Questions

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[AHLA - Health Law Hub: Current Topics \(americanhealthlaw.org\)](https://americanhealthlaw.org)  
[AHLA - Annual Meeting](#)

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