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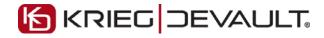
Name	Speaker	Planner	Commercial Interest/ Content Validity	Role/Nature of Financial	What I Received	Conflict/Resolved
			Content valually	Relationship		
Stephanie Eckerle, JD Partner Krieg DeVault	Х		No relevant financial relationships with any commercial interests	N/A	N/A	None
Brandon Shirley Senior Associate Krieg DeVault	Х		No relevant financial relationships with any commercial interests	N/A	N/A	None
Jessica Davis CME Coordinator Indiana State Medical Association		Х	No relevant financial relationships with any commercial interests	N/A	N/A	None
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About Our Speakers



Stephanie T. Eckerle seckerle@kdlegal.com 317.238.6373 Office

Stephanie Eckerle devotes her practice to representing businesses in an array of healthcare matters. Within the healthcare industry, Ms. Eckerle focuses her practice on providing regulatory, compliance and corporate advice to physicians, practice groups, hospitals, pharmacies, on-site employer healthcare clinics and other healthcare institutions. She counsels these clients on an array of regulatory matters, including telemedicine issues, pharmaceutical matters, reimbursement issues, fraud and abuse issues and licensure matters. In addition, Ms. Eckerle counsels healthcare providers and health plans on HIPAA and state privacy laws, including the identification, investigation and remediation of breach incidents, compliance programs and health information technology issues. Within the healthcare arena, Ms. Eckerle also works with employers to implement health and wellness programs for their employees, which includes counseling on occupational health and wellness initiatives, worker's compensation issues and the implementation of on-site employer clinics.





About Our Speakers



Brandon W. Shirley bshirley@kdlegal.com 317.238.6229

Brandon W. Shirley is a member of the firm's Health Care Practice Group. His practice areas include Medicare and Medicaid compliance, drafting, reviewing, and negotiating transactional agreements, state surveys and corrective action plans, Federal and State pharmacy laws and requirements, and administrative litigation. Mr. Shirley also has specialized experience with Corporate Integrity Agreements, including implementation, policy drafting, and compliance.

Mr. Shirley brings significant experience in the areas of preventive compliance, responding to adverse government agency actions, and transactional work. Mr. Shirley has extensive experience with State and Federal Medicaid laws, regulations, and policies. Mr. Shirley is well acquainted with the internal workings of the State Medicaid program due to his previous position as the Deputy General Counsel of the Family and Social Services Administration. Mr. Shirley regularly advises on issues regarding Medicaid and Medicaid managed care reimbursement, telehealth and telemedicine, Medicaid waiver programs, Medicaid pharmacy laws and requirements, and handles many other related issues and transactions. Mr. Shirley has specific experience with Federal and State opioid prescribing limitations and requirements on providers in Indiana.

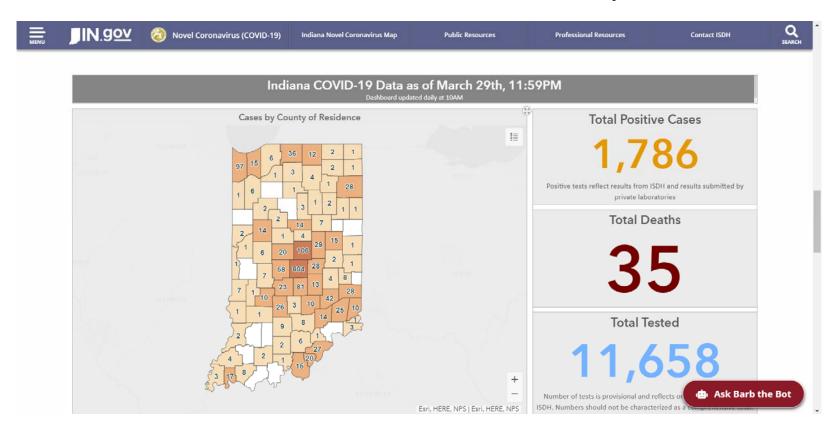




Telemedicine: The New Frontier During COVID-19

- Why Telemedicine?
- Federal and State Public Health Emergency Declarations
- Federal expansion of Telehealth Services
 - □OIG cost-sharing waivers and free services
 - □ DEA controlled substances
 - OCR HIPAA
 - ☐ Effect of these changes on Indiana telehealth/telemedicine
- Indiana expansion of Telehealth Services
 - ☐ Governor Holcomb Executive Orders
 - ☐ Licensure changes
 - ☐ Indiana Medicaid coverage changes
- Prescribing controlled substances federal and state impact

COVID-19 Cases in Indiana as of March 29, 2020



Why Telemedicine? CDC and ISDH Guidance

"Nurse advice lines and *telemedicine* can screen and manage patients with suspected COVID-19 without the need for the [health care provider] to use respiratory protection. Promoting the use of these technologies and referral networks can help triage persons to the appropriate level of care, potentially reducing the influx of patients to healthcare facilities seeking evaluation."

CDC: Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 (COVID-19) in Healthcare Settings. https://www.cdc.gov/coronavirus/2019-ncov/infection-control-control-recommendations.html

CDC: Strategies for Optimizing the Supply of N95 Respirators: Conventional Capacity Strategies, https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/conventional-capacity-strategies.html

ISDH: COVID-19 Strategies for Optimizing PPE Use and Re-Use, https://coronavirus.in.gov/files/COVID-19 Strategies%20for%20Optimizing%20PPE REUSE%20Guidance 03.17.20.pdf

Key Dates

- January 31, 2020: HHS Secretary Alex Azar declares a public health emergency, effective Jan. 27, 2020. https://www.hhs.gov/about/news/2020/01/31/secretary-azar-declares-public-health-emergency-us-2019-novel-coronavirus.html
- March 6, 2020: Indiana Governor Eric Holcomb declares a public health emergency in Indiana Executive Order 20-02.
- March 13, 2020: President Donald Trump declares a national emergency beginning March 1, 2020. https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/

Key Dates

- March 17, 2020: CMS waives certain telehealth restrictions.
 https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet
- March 19, 2020: Indiana Governor Eric Holcomb issues Executive Order 20-05, which directs agencies to waive certain legal requirements, including restrictions on telemedicine.
- March 26, 2020: Indiana Governor Eric Holcomb issues Executive Order 20-12.
- March 30, 2020: Indiana Governor Eric Holcomb issues Executive Order 20-13, which suspended certain Indiana telemedicine requirements.

Governor Holcomb Executive Orders: https://www.in.gov/gov/2384.htm

Effect of Public Health Emergency Declarations

Federal and State waiver authorities:

- Section 1135 (42 U.S. Code § 1320b–5). HHS Secretary may temporarily waive certain legal requirements related to reimbursement for federal health care programs, e.g., Medicare, Medicaid, and CHIP.
 - Does not impact State laws/regulations
- Ind. Code 10-14-3 Governor may temporarily waive certain legal requirements after declaring a public health emergency.
- Requirements not otherwise waived remain in effect.
- Both waivers are temporary and end upon the conclusion of the public health emergency declaration.

Medicare: Changes to Telemedicine During Public Health Emergency

- Medicare Telemedicine Health Care Provider Fact Sheet, March 17, 2020: https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet
- Additional Background: Sweeping Regulatory Changes to Help U.S.
 Healthcare System Address COVID-19 Patient Surge, March 30, 2020:
 https://www.cms.gov/newsroom/fact-sheets/additional-backgroundsweeping-regulatory-changes-help-us-healthcare-system-address-covid-19-patient

Medicare: Changes to Telemedicine During Public Health Emergency

- Effective Date: March 6, 2020
- Location Expansion:
 - Medicare will pay for a telemedicine encounter when the patient is at a provider's office, hospital or the patient's residence.
 - No limitation on geographical areas.
 - Previously limited to designated rural areas and patient had to be at a clinic, hospital, or certain other types of medical facilities for the service.
- Provider Expansion:
 - Medicare will reimburse for telemedicine services provided by doctors, nurse practitioners, clinical psychologists, and licensed clinical social workers

Medicare: Types of Virtual Services

- Telehealth
- Virtual Check-ins
- E-Visits

Medicare: Telehealth

- Provider must use an interactive audio-video telecommunication system that permits real time communication, which aligns with Indiana law.
- These visits are considered the same as in-person visits and are paid at the same rate as regular, in-person visits.
- Medicare co-insurance and deductibles generally apply to these services except to the extent covered in the OIG Policy Statement (discussed herein).
- Available to physicians, nurse practitioners, physician assistants, nurse midwives, certified nurse anesthetists, clinical psychologists, clinical social workers, registered dietitians, and nutrition professionals.

Medicare: Virtual Check-Ins

- Brief communication with a patient via a number of communication technologies, including telephone. Note that Indiana law now also allows telephone communications under Executive Order 20-13.
- CMS expects that the virtual service will be initiated by the patient, but providers should educate patients on the availability of the service.
- Virtual check-ins can be provided to both new and established visits.
- The communication cannot be related to a medical visit within the previous 7 days and does not lead to a medical visit within the next 24 hours (or soonest available appointment).

Medicare: E-Visits

- Non-face-to-face, patient-initiated communications with an established patient and their doctors without going to the doctor's office by using online patient portals.
- Patient must verbally consent to receive virtual check-in services.
- The patient must generate the initial inquiry and communications can occur over a 7-day period
- Not limited to any geographical area.

TYPE OF SERVICE	WHAT IS THE SERVICE?	HCPCS/CPT CODE	Patient Relationship with Provider
MEDICARE TELEHEALTH VISITS VIRTUAL CHECK-IN	A visit with a provider that uses telecommunication systems between a provider and a patient. A brief (5-10 minutes) check in with your practitioner via telephone or other telecommunications device to decide whether an office visit or other service is needed. A remote evaluation of recorded video and/or images submitted by an established patient.	 Common telehealth services include: 99201-99215 (Office or other outpatient visits) G0425-G0427 (Telehealth consultations, emergency department or initial inpatient) G0406-G0408 (Follow-up inpatient telehealth consultations furnished to beneficiaries in hospitals or SNFs) For a complete list: https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes HCPCS code G2012 HCPCS code G2010 	For new* or established patients. *To the extent the 1135 waiver requires an established relationship, HHS will not conduct audits to ensure that such a prior relationship existed for claims submitted during this public health emergency For established patients.
E-VISITS	A communication between a patient and their provider through an online patient portal.	994219942299423G2061G2062G2063	For established patients.

See CMS Medicare Telemedicine Health Care Provider Fact Sheet

Telemedicine Coverage by Private Insurers

- Some private insurance companies are starting to amend their policy requirements to allow for greater telehealth flexibility.
- IDOI Bulletin 252 (3/26/20) encourages use of telemedicine and related cost-sharing for private insurers.

https://www.in.gov/idoi/files/20200326%20Bulletin%20252%2 0eo05%20final.pdf

HIPAA: Office for Civil Rights

- OCR will not impose penalties for noncompliance with certain HIPAA Rules in connection with the "good faith provision" of telehealth during the COVID-19 nationwide public health emergency.
 - Applies to telehealth provided for any reason.
 - Applies to health care providers only.

Does NOT apply to application of HIPAA Rules to other areas of healthcare outside of telehealth during the public health emergency.

HIPAA: Office for Civil Rights

- Permitted Technology: Non-public communication technology, including:
 - ✓ Apple FaceTime
 - ✓ Facebook Messenger video chat
 - ✓ Google Hangouts video
 - ✓ Skype
 - ✓ Certain Texting Applications: (Signal, Jabber, Facebook Messenger, Google Hangouts, Whatsapp, or iMessage)
- Indiana law requires all videoconferencing used for telemedicine to be "secure".
- Prohibited Technology:
 - × Facebook Live, Twitch, TikTok, and similar video communication applications.

HIPAA: Office for Civil Rights

- Providers are encouraged to notify patients that third-party applications potentially introduce privacy risks.
- Providers should enable all available encryption and privacy modes when using such applications.
- Providers should always use private locations and patients should not receive telehealth services in public or semi-public settings, absent patient consent or exigent circumstances.

HHS OCR Resources: https://www.hhs.gov/hipaa/for-professionals/special-topics/hipaa-covid19/index.html

HHS: Office of Inspector General

- Physicians and other practitioners have the option to, but are not required to, reduce or waive cost-sharing obligations (co-insurance and deductibles) Medicare beneficiaries may owe for telehealth services furnished consistent with the then applicable coverage and payment rules.
- Must bill only for services actually performed.
- Must comply with legal authorities related to proper billing, claims submission and cost reporting.
- The OIG reserves the right to reconsider, modify or terminate the Policy Statement.
- OIG Policy Statement: <u>https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/policy-telehealth-2020.pdf</u>

Indiana Law: Telemedicine

IC 25-1-9.5-6

Telemedicine is the delivery of health care services via

- secure videoconferencing;
- interactive audio-using store and forward technology;
- remote patient monitoring technology; or,
- audio only (pursuant to Executive Order 20-13 and only during the public health emergency declaration).

Executive Order 20-13: https://www.in.gov/gov/files/Executive%20Order%2020-13%20Medical%20Surge.pdf

Waivers of Indiana law: Telemedicine Licensure

- Effective only during the public health emergency.
- Mental health providers are permitted to practice telemedicine.
- Physical therapist, speech therapist and occupational therapist are permitted to practice telemedicine via audio-visual means only.

Executive Order 20-05: https://www.in.gov/gov/files/EO 20-05.pdf Executive Order 20-13:

https://www.in.gov/gov/files/Executive%20Order%2020-13%20Medical%20Surge.pdf

Waivers of Indiana law: Telemedicine Licensure

- Out-of-state provider not required to hold an Indiana license for telemedicine services provided in Indiana. However:
 - The person cannot be suspended or barred in other state and must hold an equivalent license.
 - Executive Order 20-13 allows for a temporary license for out-of-state providers and other unlicensed professionals to provide health care services in Indiana (must register with the PLA).
 - Out-of-state providers of telemedicine services should check with the PLA for registration or other necessary filings.

Indiana Law: Telemedicine for Medicaid Beneficiaries

Changes during Indiana's public health emergency:

- ✓ Medicaid will allow for real-time, interactive consultation between the provider and the patient via computers, phones, television monitors and other voice-only communication. Non-voice communication such as emails or text messages are not permitted.
- ✓ Changes apply to traditional Medicaid and Medicaid managed care.
- ✓ The patient can be located in their home during the telemedicine encounter.
- Medicaid telemedicine will not cover: surgical procedures, radiological services, laboratory services, anesthesia services, audiological services, chiropractor services, care coordination without the member present, durable medical equipment (DME)/home medical equipment (HME) providers, and provider-toprovider consultation.

Indiana Law: Telemedicine for Medicaid Beneficiaries

IHCP Bulletin, March 19, 2020:

http://provider.indianamedicaid.com/ihcp/Bulletins/BT202022.pdf

IHCP Webinar, March 23, 2020:

https://www.in.gov/medicaid/providers/1014.htm

Federal Law: Controlled Substances Prescribing via Telemedicine

- During the public health emergency and beginning March 23, 2020,
 DEA-registered practitioners may prescribe controlled substances via
 telemedicine to patients in states in which they are not registered with
 the DEA.
- Practitioners are not required to apply for this exception from DEA regulations.
- Subject to all terms of DEA Letter dated March 25, 2020, https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-018)(DEA067)%20DEA%20state%20reciprocity%20(final)(Signed).pdf

Federal Law: Controlled Substances Prescribing via Telemedicine

During the public health emergency, practitioners can prescribe controlled substances through telemedicine without a prior in-person visit when:

- The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice;
- The telemedicine communication is conducted using an *audio-visual*, realtime, two-way interactive communication system; and
- The practitioner is acting in accordance with applicable Federal and State law.

DEA COVID-19 Information Page: https://www.deadiversion.usdoj.gov/coronavirus.html

Indiana Law: Controlled Substances Prescribing via Telemedicine

- Executive Order 20-13 suspended Ind. Code 25-1-9.5-8(b).
- Allows a DEA registered practitioners to issue prescriptions for all Schedule II-V controlled substances to patients for whom they have not conducted an inperson medical evaluation; provided:
 - prescription is for a legitimate medical purpose and practitioner is acting in the usual course of professional practice;
 - communication is via audio-visual, real-time, two—way interactive communication; and
 - all applicable federal and state laws are followed.

Key Takeaway: Controlled Substances can only be issued via telemedicine when audio-visual communication is used.

Indiana Law: Prescribing via Telemedicine

For non-controlled substances prescribed as maintenance medication:

- Suspension of restriction on a refill be limited to no more than the quantity on the most recent refill or a 30 day supply, whichever is less; and,
- Permits a one-time 90-day emergency refill.

Thank you for participating!

Please be sure to complete the program evaluation in order to receive credit

Questions?



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For additional COVID-19 Updates, visit https://www.kriegdevault.com/info/coronavirus-covid--resource-center.

DISCLAIMER:

The contents of this presentation should not be construed as legal advice or a legal opinion on any specific facts or circumstances. The contents are intended for general informational purposes only, and you are urged to consult your own attorney concerning your situation and specific legal questions you have.



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