Air Ambulance Quality and Patient Safety (AAQPS) Advisory Committee Public Meeting #1 – Meeting Transcript

December 12, 2024

-Good morning, everyone. My name is David Wright. I'm with the Centers for Medicare & Medicaid Services. It's my pleasure today to open the first meeting of the Air Ambulance Quality and Patient Safety Advisory Committee.

This meeting is being held pursuant to a notice published in the Federal Register on November 27, 2024. The agenda was posted on the AAQPS Committee website.

I'm the Designated Federal Officer responsible for compliance with the Federal Advisory Committee Act under which this meeting is being conducted. It's my responsibility to see to it that the agenda is adhered to and that accurate minutes are kept. I also have the responsibility to adjourn the meeting should I find it necessary to do so in the public interest.

Only AAQPS Committee members may participate in any discussions and vote on manners put to a vote by the chair. This meeting is open to the public, and members of the public may address the AAQPS Committee with the permission of the chair. The chair may entertain public comment if, in his judgment, doing so will not disrupt the orderly progress of the meeting and will not be unfair to any other person. Members of the public are welcome to resend written material to the Committee at any time.

With that, it's my pleasure to turn this meeting over to Jeffrey Richey, who is the Chair of this Committee. Jeff?

-Thanks everyone, and I appreciate everyone joining our group here. So, I'd like to introduce myself.

My name is Jeffrey Richey, and I am the chair of the AAQPS Committee. My background is I'm the executive director at Airlift Northwest, a part of University of Washington “UW” Medicine. I am also, Associate Administrator at Harborview Medical Center. And my background is I've been a flight nurse for almost 34 years, and a hospital executive for the last 15 years.

So, in order to be able to keep things moving I'd like to be able to welcome our next AAQPS committee member, Dr. William Hinckley. Can you please introduce yourself?

-Thanks, Jeff. Good morning. Bill Hinkley, I am a flight physician and medical director of UC Health Air Care and Mobile Care in Cincinnati. I am a professor of emergency medicine and an ER doc at the University of Cincinnati. I am also EMS board certified and medical director of several fire departments. And I am past president of the, the air medical physician association (AMPA).

-Thank you, Dr. Hinckley, for the introduction. Now we'll move to our next AAQPS Committee member and appointed accrediting bodies representative, Eileen Frazier. If Eileen is not on, I will move on to our next one. We can just come right back to you.

Alright, so thank you. So, let's go on to our next member, who is our additional HHS representative Dr. Mark Gamber.

-Hey, good morning. Thank you for allowing me to participate. My name is Mark Gamber. I'm a practicing emergency physician. I am the Chief Medical Officer for Alacura Medical Transport Management, and I am a ground EMS medical director as well, board certified in emergency medicine and emergency medical services. Thank you.

-Thank you, Dr. Gamber. The next, AAQPS member I'd like to be able to introduce is Dr. Jordan Pritzker.

-Good morning, I'm Jordan Pritzker. I'm an executive medical director and medical policy operations group at CVS Aetna and I oversee our out of country air ambulance transport and much of our domestic air ambulance services. Thank you.

-Thank you for your induction, Jordan. Our next AAQPS Committee member and appointed state insurance regulator, Commissioner Grace Arnold.

-Hi, everyone. It's a pleasure to be here. My name is Grace Arnold. I'm the commissioner of the Minnesota Department of Commerce, which is the regulatory body that oversees insurance in the state of Minnesota. I also sit on a number of committees at the National Association of Insurance Regulators and mostly on the health side. I have a background in health insurance and was an employee of CMS a while ago. I've been commissioner for about four years, and I'm excited to be a part of this group.

-Thank you for your introduction, Grace. Now we'll move to our next AAQPS Committee member and appointed DOT designee Robert Reckert.

- Good morning and good afternoon, everyone. My name is Robert Reckert, and I am here representing the Department of Transportation and the Federal Aviation Administration. I

am the manager of the Air Transportation Division within the Federal Aviation Administration's Office of Aviation Safety. Applicable to this Committee, I am responsible for the regulations and operational policy surrounding part 135, including helicopter air ambulance operations. I'm a retired master army aviator, former helicopter ambulance part 135 pilot, and I am the FAA co-chair for the US helicopter safety team.

-Alright, thank you for the introduction, Robert. Now we'll move to our next AAQPS Committee member and DOT appointee, Ben Clayton.

-Hey, good morning, everybody. My name is Ben Clayton. I'm the CEO of Life Flight Network. We're a not-for-profit air ambulance provider with about 50 or so, Rotary Wing helicopters and fixed-wing. And my background is as a pilot for close to 20 years. I started flying in the Marines and have done some of the same flying I did as a Marine as well as an air ambulance.

-Thank you for your introduction. Ben. Now we'll move to our next AAQPS Committee member and DOT appointee, Jim Houser.

-Hi, good morning, everyone. My name is Jim Houser. I currently serve as the President of the Center for Emergency Medicine of Western Pennsylvania Inc. We are a service of UPMC, which is a large academic based medical center system in Pittsburgh, Pennsylvania. Stat MEDVAC is the transport arm in the center where we own and operate our own air carrier certificate, operating 18 helicopter bases across the region and serving the area with several critical care ground units. In addition to serving as part of the executive team for the Center, I have a clinical background starting as an EMT, paramedic nurse and now nurse practitioner. I am also currently serving as the chair of the Association of Air Medical Services Board of Directors, and I'm looking forward to working with this group and serving our industry.

-Thank you for your introduction, Jim. Now we'll move to our AAQPS Committee member and DOT appointee, Tom Judge.

-Thanks, Jeff. Good morning. I'm Thomas Judge. I founded LifeFlight of Maine, and we have our own Air Certificate Life Flight Aviation Services, former president chair of Association of Air Medical Services and for the Association of Critical Care Transport. Thanks.

-Thanks, Thomas. Now we'll move on to our next AAQPS Committee member and DOT appointee, Paul Julander.

-Hey, good morning, ladies and gentlemen, Paul Julander. I serve as the Chief Operating Officer for PHI Health and PHR medical, 135 operation and roughly a 119 aircraft across the

United States. Twenty years in the flight career, about 10 in the ground career as a paramedic. Pleasure to be here.

-Thanks, Paul. Now we'll move on to our next AAQPS Committee member and DOT appointee, Jason Quisling.

-Thank you and good morning, I'm Jason Quisling. I'm the Senior Vice President of Flight Operations and AirCom with Air Methods. I've been a pilot for about 35 years, approximately 25 of those years in the air medical field. I'm a member of the US helicopter safety team, and a board member for the Air Medical Operators Association. Thank you.

-Thank you for your introduction, Jason. Now we'll move to our final AAQPS Committee member and appointed patient advocate of the group, Colonel Steve Coffee.

It doesn't look like Colonel Coffee is on, but I'll just do a quick introduction. He is a nationally recognized patient advocate with extensive personal experience, actively advocating for a family member. He will be joining us a little later in the day as we get to him. So, welcome, Colonel Coffee.

I think we'll now go into the overview of the AAQPS Committee.

The AAQPS Committee just so everyone is aware the No Surprises Act calls for the Department of Health and Human Services to establish an advisory committee to address the following topics in its deliberation and final report to Congress. These things that we have to be able to go over: qualifications of different clinical capabilities and levels of tiering all such levels; patient safety and quality standards; clinical triage criteria for air ambulances; options for improving our service reliability during poor weather, night conditions, or adverse conditions; and differences between air ambulance vehicle types, service and technologies and other flight capability standards and the impact of such differences on patient safety.

Next slide. So, the purpose of why we're all gathered here is really to review the options to improve quality patient safety and clinical capability standards for each clinical capability of air ambulances. The outcome that we are driving towards is to define innovative approaches to improving quality, accessibility, affordability, and sustainability of air ambulance services for safe quality healthcare.

Our Subcommittee and Committee voting there will be two Subcommittees, that will inform the main Committee.

First off is Clinical Standards. They are going to be looking at the qualifications of different clinical capabilities and tiering of such levels, patient safety and quality standards and then clinical triage criteria for air ambulances. These [Sub]committee members were selected from those who applied to the main Committee and then our second Subcommittee is Flight Safety.

And that Committee is going to be looking at all options for improving service reliability during poor weather, night conditions and other adverse conditions. Also, they'll be looking at differences between area ambulance vehicles, type services, technologies and other flight capability standards and the impact of such differences on patient safety. The members are Department of Transportation appointees on the main AAQPS Committee and they will serve in that Subcommittee. Next slide, please.

One thing I did forget to mention is that on the voting side, we will be striving towards consensus on the recommendations that we bring forward, and then if we are unable to be able to reach consensus and time does not allow, we will vote on those recommendations.

Just wanted to be able to make sure that everyone was clear on how we were going to be able to go about our business. Next slide, please.

Thank you. So, the advisory Committee meeting schedule. This is kind of where we're going to be today is December 12th and we will be going through those priorities looking at the topics for discussion and in-depth review and then also looking at future recommendations, and we have established what the Subcommittee expectations are.

In January of 2025, Flight Safety Subcommittee is going to be meeting and same thing with the clinical standards. February 18th will be coming back for a full Committee meeting to review issues that have been identified by Flight Safety Subcommittee and the Clinical Standard Subcommittee and then prioritizing those areas for recommendation. And then March and April, Flight Safety and then the Clinical Standards (sub)Committee will be meeting and drafting recommendations for the Committee and then May 8th we will be coming back as a full Committee to vote and finalize recommendations for a report to Congress and then the report to Congress will be due in May to June.

Okay, what I'd like to be able to do next is I would like to be able to get our first speakers.

Jana Williams is the President and CEO for the Association of Air Medical Services (AAMS) and the MedEvac Foundation International (MFI), the air medical trade organization and its charitable organization respectively. Jana has more than 30 years of experience in EMS, incident management, and air medical communities and enjoys gathering perspectives from many vantage points.

She is joined by Jason Quisling, who has been flying commercially for more than 30 years in both fixed-wing and rotorcraft. For the last two decades he has been working in the Helicopter Air Ambulance field and is currently serving as the Senior Vice President of Flight Operations, Maintenance and AirCom Communications for Air Methods, overseeing a fleet of 400 aircraft, 600 maintenance technicians, and 1,200 pilots. Welcome Jason and Jana.

-Thank you.

-Thank you, Jeff. Very humbled and honored to be here to represent, and I'm grateful that we're virtual as you can hear from my voice I'm fighting off something. So, Jason has my notes in case my voice goes away. He can take over at any minute. But if we could have the next slide, please.

-Born out of military battlefield use, air medical has evolved over the last several decades. Air medical not only describes moving patients to care, what we refer to as medical evacuation or medevac, but also moving skills, resources, and care to patients or what we refer to more as critical access or advanced in critical care. For example, bringing blood to a patient where it is not immediately available. Generally, this involves fixed and rotor wing aircraft or planes and helicopters, but it can also involve transitioning to ground ambulances, especially in inclement weather or when larger teams are necessary.

When air medical 1st started in the U.S., helicopters were placed at large primary academic hospitals. They were fewer and they generally had longer transport and response times.

In the late 1990's and early 2000's as cardiac and stroke care evolved to understand that time means muscle or brain, a concept called out basing took shape and helicopters, and aircraft were removed off of main hospitals and placed out closer to the patients even in rural areas. Today, 86% of the U.S. lives within 20 minutes of an air medical asset, which is critical when we talk about outcomes in time-sensitive conditions such as cardiac, trauma, neuro, burn, and even complex obstetrics. Next slide, please.

Air ambulances can be utilized in a variety of ways, primarily though, the scene response refers to landing at or near a patient, not at a medical facility, i.e., at the side of a road of a car accident or in a snow field in Alaska for a patient in labor.

Interfacility transports are just that, between facilities, and largely from one level of care to a higher one. Specialty transports usually refer to specific teams with specific equipment, such as neonatal teams with an isolate. Air ambulances are utilized to move organ

harvesting, resources, and can be utilized to support mass casualties as well. Typically moving patients farther away from the event, the ground ambulances, or during disasters, such as when ground ambulance transport is not available. Next slide.

-Generally, rotor wing aircraft are used for transports within 150 nautical mile radius. However, on occasion we do stretch them further and we can see individual legs of up to 200 nautical miles at times. This often requires multiple fuel stops and therefore it adds time to the overall transport and is generally not favorable.

For longer transports, we switch to fixed-wing aircraft. Turboprop fixed-wing aircraft are used primarily between a hundred nautical miles and a thousand nautical miles. Occasionally, we will also have those aircraft stretch out as far as 1,200 nautical miles, but flight time and duty day issues start to become critical to the transport of the patient. Oftentimes, if we have transports that require greater than a 1,000 nautical miles in length, we will move to jet aircraft due to their ability to handle longer distances. Sometimes jet aircraft are also preferred because of their ability to fly above much of the weather systems that we can see. Helicopters are capable of instrument flight and operating in reduced visibility in lower weather, but this does come with some limits in terms of range, the availability of alternates for the helicopters to fly to, and environmental conditions such as icing and thunderstorms, which will prevent flights in the helicopters.

One advantage that helicopters do have in weather operations is that it's possible to develop GPS approaches to arrive and depart directly from the hospital helipads themselves and save the additional time that it takes and the logistics around ground transport.

Issues that helicopters have in being able to fully utilize this infrastructure are the infrastructure itself is not prevalent across the U.S. It has to be built out individually by operators and the helicopters themselves have greater sensitivity to gross weights, center of gravity issues, and vertical obstacle clearance while conducting these approaches because they're much closer to the obstacles than say if we were flying into an airport environment. Next slide, please.

-So, we.

-Sorry, Jana, go ahead.

-Jason, we might have skipped a slide here.

-Okay, so for our, organizational models, air ambulances operate under a variety of business models. The hospital-based model or sometimes referred to as traditional

programs because this is how the initial U.S., air ambulance industry came into being. We generally have an FAA part 135 operator's certificate, provide aviation and maintenance, and the hospital provides the clinical care as a traditional healthcare partner – the equipment, personnel, medical licensing.

A second way of providing services, referred to as community-based model, and this is a little bit more of a turnkey operation that comes directly from the FAA Department 135 operator, provides all aspects of the program, all of the aviation, all of the maintenance, all the clinical, all of the patient interactions will revolve around that drop-in based team that can transport a patient.

And then, in the commercial sector, the alternative/hybrid models, this is a blend of the traditional-based, hospital-based model, and the community-based model. There will be partnership between the Part 135 operator, and hospital or community healthcare system to determine which parts of the process are going to be the responsibility of one or the other.

Finally, we have a model that involves public safety use, and so this would be municipalities, government owned agencies, that are cross utilized for police, fire, homeland security use, and air medical evacuation. Next slide.

The regulatory framework for air medical is very complex. We are extremely highly regulated, and we have extensive surveillance for the material and the large operators. The FAA often has dedicated teams for each certificate. As an example, my company, Air Methods with only 400 aircraft is viewed as having the same complexity as the 5th largest airline by the FAA. Therefore, we have a certificate management team dedicated to our certificate of approximately 42 FAA inspectors. They are embedded with us and everything we do from training to operations.

Expectations and standards are the same for operators with 9 or fewer aircraft, but the oversight of those operators is not going to reach the same levels, just due to resources. Major investments in training and equipment and systems are required to meet the regulatory minimums. However, due to the complexity of the operations for Air Medical, this is often just the beginning of the requirements and costs, and additional investments are needed to reach acceptable risk levels for the service areas that we have and to transport our patients safely.

Many operators participate in numerous voluntary safety programs with the FAA, and many are active members of aviation rulemaking committees in efforts to try and be proactive stewards of safe outcomes. Next slide.

-There is a wide array of staffing models utilized in the US. As far as aviation goes, aircraft are operated generally by a single pilot. Some do have dual pilots. This is more common with fixed-wing or planes. Aircraft maintainers or mechanics specific to aviation who check and maintain aircraft to FAA, company, and Airframe standards.

When it comes to clinical crews, most have two clinical providers with the patient unless aircraft performance limits that on very rare occasions. Standard clinical crews are typically nurse-paramedic, nurse-nurse, or nurse-physician. Specialty teams are cross trained to perform specialty functions in an aircraft. Many specialty teams are designed to bring tertiary and quaternary care to the patient. Next slide, please.

Clinical capabilities are advanced. I'm sorry. Go ahead, Jason.

-No problem, Jana. So, vehicle selection criteria is often a balance between cost, capacity, performance, and safety. Speed, range, and cabin size drive the prices of the aircraft exponentially. Twin engine rotor wing aircraft are currently preferred for longer range flights, specialty team flights, over water, or instrument flight operations. Single engine is more common for mid-range or short-range operations. There are more options arriving every day that allow single engine aircraft access to instrument flight operations and somewhat longer range operation flights are possible in the single engine helicopters at reduced payloads.

Fixed-wing options are primarily balanced between speed and range, and we will also consider the option to fly above the weather in jets as previously mentioned. Many operators work directly with aircraft manufacturers to drive performance and development and safety enhancements for the aircraft. While we've been successful in evolving greater capabilities in aircraft and greater safety in the air medical fleet, it often does not move at the pace of industry and at times becomes cost prohibitive to make such changes. Additionally, from a speed perspective and trying to make these changes, it can be hindered by availability of FAA resources on certification efforts. Next slide.

There are a variety of safety considerations that we take into account every day to try and move patients safely. Considerations and interventions to maintain an environment suitable for patient care involves temperature regulation and extremes, minimizing vibration and turbulence impacts, as well as how we package or place the patients in the aircraft, for that transport. The interior that supports medical access and safe structures to make sure that everything is restrained, options for oxygen, suction and power are built into the interior spaces, essentially creating a flying hospital room.

Clinicians that are flying on aircraft frequently are trained to perform as air medical crew members. This involves limited knowledge of how to assist in emergencies, how to brief

patients on seat belts and exits, as well as effective crew coordination communications for the team.

Collaboration with industry and customer groups as well as aircraft certification drives the enhancements to the aircraft and personal protective equipment that we use for the transports. Safety Management Systems, which are central to how we both manage and judge risk, are supported through transparency and reporting and information sharing across the industry, as well as first-hand with regulators such as the FAA. All the major operators participate in multiple industry organizations and FAA safety events to share best practices and lessons learned, as well as to discuss emerging risks and constraints in the industry. Next slide.

Hundreds of millions of dollars are invested in safety by operators every year. Many of the required items were already in use by the largest operators years before they became mandated pieces of equipment. Nearly 50% of air medical operations take place during the night, and air medical operators were the first group in the US to develop civilian use of night vision goggle technology.

Collaboration with the FAA allowed regulatory change to eventually make this mainstream safety enhancement an option for operators and this has undoubtedly increased safety for the teams, the patients, and it has prevented numerous accidents during nighttime flights.

This change was not initiated through mandated regulations. It was a result of a commitment by industry to spend countless millions on equipment, aircraft modifications, training, and an effort that brought additional safety to the industry. Some safety equipment also increases the capability to provide services such as IFR, or instrument flight capable aircraft, or even autopilots in visual flight rules aircraft.

These autopilots, even when not used for dealing with weather, can assist in reducing pilot fatigue on longer flights that we may fly in a rotor wing aircraft. They also offer more options if unforecasted weather is encountered, and we have to make a precautionary landing. We're trying to exit the weather to safer conditions.

Other safety equipment is essential but not necessarily as expensive. Personal protective equipment such as helmets, flight suits, boots have all been proven to help save lives and reduce the chance of injuries in the event of an incident. Modifications to aircraft such as crash resistant fuel systems have been expensive to develop and install but, the industry, again, has driven this improvement because they understand the immense safety value it provides in reducing the risk to occupants of post-accident fire. Additionally, we have seen a great investment in flight simulation training and especially the use of level D full flight

simulators to train our pilots to make the best decisions in dynamic conditions and have the safest operations in the most reliable operations we can. Next slide, please.

Communication centers are a vital link in the way we conduct flights and maintain contact with our aircraft as well as handle the dynamics of the missions they perform. The communication center is the place where we receive a request to perform patient transport. They will coordinate finding the closest most appropriate team that can deliver that patient to the medical care facility. Patient condition, changing weather, civil unrest, mechanical issues, etc., there are many reasons a flight may have to deal with unexpected conditions and sometimes divert or land short of a destination.

Communication centers help ensure that we can keep up with these developments in real time, make sure that we have the right resources in the right place for our teams and the patient, and ultimately find a way to safely deliver a patient into higher care. In addition to Com Centers, operators with 10 or more aircraft also utilize an operational control center to provide certificate oversight and flight monitoring. This often increases the level of control associated with the initiation of any flight and it ensures additional risk analysis has been performed to properly manage the risks involved in those operations at the start of the flight and as they change. Next slide, please.

-Clinical capabilities are advanced. States and accrediting bodies require significant experience of providers before they can be considered for air medical. Clinicians generally have at least three to five years of critical care and/or emergency experience before air medical training occurs. Broad expertise across medical specialties is the norm, as they can be expected to care for patients from age zero through the lifespan. Continuing education is also required and includes training specific to the program's patient population. Education happens in a variety of ways, but is generally competency-based, largely utilizing high fidelity human patient simulation. Clinical quality reviews of care are generally required by a physician. Clinical teams are also required to undergo aviation training both initially and ongoing, primarily focused on safety. Specific certifications also exist including for leaders of the air medical programs. There are a few examples of the certifications on this slide. Next slide, please.

Some of the key challenges include high fixed operational costs. We call it the price of ready. Teams and aircraft have to be ready at any given moment to respond to nearly anything from an obstetrical emergency to a child not breathing, to a hospital evacuating its patients during a hurricane. There are regulatory complexities when you operate at the intersection of aviation, transportation, public safety, and healthcare.

It is far too simple to say that the feds regulate the front, and the state governs the back of any air medical aircraft and team. Air medical does not stop at county or state lines. I gave

you a quick overview, but there are significant initial and ongoing safety and training requirements of all involved in medical transport.

Equipment both in aviation and clinically, thankfully continuously evolves but requires significant investment to adopt and in many cases to continue, get certified, and be added to specific airframes such as STC requirements. There are manufacturing and supply chain issues, and there are complex sometimes austere, logistical, infrastructure, and environmental considerations as well. Next slide, please.

In conclusion, we want to recap the importance of air medical services as a safety net for access to critical care and especially in rural areas. We do want to share that prevailing research demonstrates positive patient outcome enhancements with air medical use in this country. You have seen there is no one operational or staffing model or airframe universal to air medical and, we believe that many factors influence this, such as geography and specific patient populations.

We have highlighted the significant focus on safety, leveraging both technology and training. And finally, we share that air medical transport isn't just about transport. It's a compelling resource in the healthcare ecosystem, largely available within minutes, 24 -7, 365.

One of our members challenged us to start thinking about air medical teams and aircraft more like critical access hospitals are seen in the US only without the brick-and-mortar challenges, mobile critical access beds and teams, if you will. It's also important to note that air medical resources cannot self-dispatch. A trained professional has to access or request our resources for them to be launched.

And with that, we'll go ahead and take any questions. I'll turn it back to Jeff.

-Thank you for the presentation, Jana and Jason. We'll hold any questions to after our last speaker here.

Now we'll move on to our next speaker who will provide the patient perspective. Joshua Cools is the director of the trauma service line for Memorial Hermann Health System in Houston and serves as a board chair for the Association of Critical Care Transport (ACCT). Mr. Cools has been in EMS for over 25 years and spent the last 14 working as a flight paramedic with Memorial Hermann Life Flight.

Welcome, Joshua.

-Hey, good morning. Thank you for having me here and allowing me the opportunity to serve as a patient advocate. As you said, my name is Josh Cools, representing both ACCT and then the Memorial Hermann Life Flight side. Next slide.

We can talk about a little bit more about learning about ACCT and then really, so I like to throw this slide because it one it adds a personal touch and two, it's exactly why we're here, right? We say we are here for patients, it's our family and our friends, you know, ultimately, we think that we will always be here to care for all the loved ones that we have. But the goal for this is to establish a platform and policies and procedures and oversight to ensure that we're taking care of everybody at all times, regardless of whether we have direct intervention or not. Next slide.

When it comes to ACCT, the important thing of this is understanding that our goal here today is to fill the voice of the critical care transport patients both ground and air. Our mission is to lead the critical care transport industry to ensure the best interests and needs of the critically ill and injured or injured patients are achieved. Next slide.

So, a little bit more about ACCT and the goal is that voice for the patients, fighting for the system, that accountability, and the policy and the regulatory table. Some more information is available on the website, ACCT for Patients – The Association of Critical Care Transport, but ultimately, we are a grassroots organization that consists of our medical and aviation committed to ensuring the same standards across the board. Next slide.

Some examples of the organizations that are part of ACCT. Go to the next slide.

When it comes to the creation of and establishment of the AAQPS, you know, this was something that ACCT was instrumental in the beginning, and we feel that it was instrumental to have this establishment of this Committee because we must make the life-saving care that we provide safer and accountable based on the quality and the reliability of it.

We'll talk a little bit about the duties which you guys are familiar with, but how that aligns with ACCT's contribution, and then the recommendations that we've made over the past few years. One of them would be the qualifications of the different clinical capability levels and the tiering and going back to the safety and the quality standards. Options for improving service reliability. The differences of the air ambulance vehicle types and the services and how that impacts the differences on patient safety. As well as the one that gets much more expanded and that's the clinical triage criteria for air ambulances.

Alright, so, this kind of just caps up the things that we're looking at, which is the quality and the patient safety, as well as establishing those clinical capability standards for each clinical capability level of air ambulances. Next slide.

So, it's imperative that we include some accident information to highlight that, you know, one of our main goals is always safety and when it comes to patient safety, first do no harm. We just have a few slides talking about the accident information over the past 20 years. Well, next slide.

This talks about the aircraft type, which is going to be part of our triage process and our clinical capability side, noticing that the air medical fatalities broken down by rotor wing and fixed-wing and the type of aircraft frames they are. Next slide.

And then addressing the fact that I think most of us know in the aviation world that human factor is the largest contributing factor for the fatal air medical accidents between 2000-2020. Next slide.

When it comes down to the aircraft frame, which we'll go to a little bit deeper here as far as the clinical capabilities each aircraft frame allows the crews to have, you can see the wide range and then the costs associated with those. With the smaller aircrafts may limiting some of the care that we can provide in the larger aircraft. The cost association might be prohibitive based on the environment that we're utilizing them. Next slide.

One of the challenges here that we're going to mention is how quality plays a factor, in the reimbursement or the relative value units with the idea that when we talk about higher acuity patients in clinical capabilities, we talk about the higher cost of aircraft and aviation safety investments that may be go beyond what the FAA minimums are. Talk about uncompensated care and then how geographical considerations play a role and the importance of how reimbursement must be associated with quality so that we're creating a stronger environment of the air medical industry to provide better care for our patients. Next slide.

So one of the standards that Eileen, I know will talk more about, the CAMTS standards that are created. In addition to that, ACCT does have some clinical care, a standard for the critical care patient. One of the challenges is that we need a common understanding of high acuity critical care transport, and the development of acceptable practice standards is and therefore ACCT has developed a set of standards. We started working on these in 2012 and our third version was completed in October of 2022, highlighting the importance that this is regardless of transport modality. Next slide.

Continuing on the clinical capability standards for air ambulance transport services. I'll refer to this as AATS moving forward, but ACCT strongly believes that the No Surprises Act established the essential platform for a system that provides reasonable reimbursement that clinical and aviation services actually provided, promotes high quality and safe air transport services, and appropriately differentiates among the varying levels of clinical and aviation capability. This charge established these varying levels of clinical capability is consistent with the National Academies of Medicine. Next slide.

When we talk about the AATS, the two main factors would be the clinical capability and the air ambulance vehicle type. The clinical capabilities determined by a number of factors that we're going to address on the next slide. And then later in the presentation, we'll talk about the ambulance vehicle types. Next slide.

When it comes to clinical capability, one of the biggest challenges that I think that we have on the Committee or that we have as an organization or an industry or society, is creating and identifying and establishing these clinical capability levels. We're proud to say that ACCT has in various circumstances provided levels that we think should be referenced to the Committee's recommendation as of how they will be established. These clinical capability levels are one through three and consistency with maybe a trauma level, level one would be the highest level of care that's being provided.

There's a lot of information. I don't think we need to read word for word, but ultimately the way we have these set up is level two is the traditional model and kind of the status quo of the air medical community now with the opportunity to have up to level one with the most advanced clinical capabilities. Next slide.

In addition to the structure, we feel that the following considerations are needed to evaluate a tiered air medical system. So, the quality and patient outcomes, patient acuity, and complexity of service as well as the medical personnel qualifications. Next slide.

To dive a little bit deeper into the quality and patient outcomes, we have the same thing that we established earlier, which is three levels. Two being the standard with the opportunity to be for level one. Mentioning that these are the outcomes that we're using. We're not just talking about aircraft frame or the medical personnel, but also the outcome of those patients that were transported. Next slide.

In addition to that, the patient acuity and service complexity, again levels one through three, level two being, your traditional potential for life threatening involved complex and critical medical, but then level one having the critically ill or injured immediate life-threatening conditions and the key with this is requiring that sophisticated specialized critical care. Next slide.

And then we'll continue by saying the medical personnels, the qualifications, how we staff our aircraft, the resources that we have, both physical and personnel on the aircraft providing care for those patients and then also the ambulance vehicle type referencing back to the AATS, the vehicle type being appropriate and conducive for those higher-level patient cares that we have. An example would be an ECMO patient or any other high acquity patient that requires additional personnel or various levels of equipment needed to care for those patients. Next slide.

In summary, ACCT has actively sought to define a tiered transport reimbursement structure that's in alignment with the capabilities of the transfer vehicle, clinical scope of service, and the clinical capabilities of the training and the staff. We as an organization applaud the work of the AAQPS on an industry-wide basis to establish long overdue clinical capability levels and overall improved patient safety. We're also happy to share our detailed work with the Committee as one of several potential building blocks for your discussion and consideration.

Next slide for any additional information. I'm happy to answer any questions. My email address is provided. Thank you for your time.

-Thanks, Josh. Appreciate the overview and your presentation.

Next, I'd like to be able to offer to welcome the AAQPS Committee members to have a discussion over the last two presentations. So, I'll just open it up to the group. We are ahead of schedule, slightly. So, I'll offer a little more time to be able to have that discussion. So, I'll just open it up to the panel.

Any questions for Jana, Josh, or Jason on the information they just presented on?

Tom?

-Yeah, thanks, Jeff. I think you have shared some of these documents. I think it would be helpful for the Committee to take a look at some of the documents that ACCT has produced because they were, you know, developed by many people across the industry. I think it would be very helpful for our discussions. To take a look at those. I have forwarded some of them to Michelle previously.

-And now I'm happy to share any other documentation. I believe you're referring to the letter that we sent in 2021, any additional documentation happy to provide.

-Any questions for Jana and Jason on the overview of the air ambulance industry?

Jim?

-Thanks, Jeff. Not so much a question, but more so a statement, as we continue to move forward in this discussion. I think the overview both that Jana, Jeff, and Josh provided just shows the complexity and the nuance that we're challenged with as we think about how we span the geography of the country and how we apply these resources in both rural and urban settings. I appreciate their time in providing that overview and don't want it to be lost on the Committee or those that are participating with us and following this discussion, that if there's any areas, really now is the time for us to ask for clarification and or to dig into it because it is a very complex way to deliver healthcare and there's not a one size fits all approach.

-Josh, maybe I could ask a question, from the chair position. The tiering that you went over, have you ran any models on how that relates back to reimbursement? Since reimbursement is very complex at times, what work have you done on that?

-Yeah, we've done some basic work on what the reimbursement would look like, different quality metrics that were put in place, but ultimately, our focus was simply saying or creating the tiered system and allowing others at different levels to talk about the reimbursement. We have some ideas. I'd be happy to share with you more detail. I want to reconnect with the group, but our main focus was just establishing this tiered quality expectations.

And I do see a question. I see the question in the box should I ask about the geographical areas?

-I think go ahead and answer it. Josh, thanks.

-So, one of this is, looks like your anonymous attendee said, one was talking about the reimbursement model we just mentioned, and the other was talking about whether all geographical areas in need of the same level of care, such as the level that we just presented.

I don't think in my opinion that all geographical areas would have the opportunity to have the same level of care across the areas. As population decreases as volume decreases, I think it becomes very difficult to provide that at this state in our industry. I would hope that eventually that we're able to provide that high level of care across the board, but it may be cost prohibitive unless some opportunities change on that reimbursement model.

-Just, you know, from my perspective speaking from, we operate in about five states and, we are very standardized and have the same clinical capabilities in all of our bases.

-Tom?

-Yeah, thanks, Jeff. I think that one of the pieces that when we put this together is that we actually did look at maybe not the reimbursement because I think that that becomes a different discussion, but the cost of providing the services and all the tiers. I think that would go back to what we did a very deep dive into, if you're looking at these different tiers, what does it actually cost? And that hopefully translates in the future into how reimbursement works and helps, you know, certainly inform both the public payers and private payers on what that might look like. And certainly it is going to be different in different areas and that's why I think you need to think about a tiered system. That not everyone is going to produce, you know, the same level of service, shouldn't be required to, and you're going to have very different cost structures.

-Alright, thanks, Tom. Jason, you had your hand up.

-Thanks, Jeff. Yeah. Maybe to blend a little bit of what Tom and Ben were saying, I think on the one hand, we do see in different geographic areas a need for different solutions to provide the right services to the communities. I wouldn't want to get lost in there though that I think anywhere in the country where we have air medical services, they are so complex and offer so many levels of service even if you look at a different type of tiering model. The teams and staff, these aircraft are capable of providing a wide range of medical care and more so every day as we start to miniaturize some of the specialty equipment that can go on the aircraft. So, I don't want to overlook that because it does lead into, maybe, if you had a tiering model per se, you know, your lowest tier aircraft instills major cost that has to sit on the ground to be ready to respond to a wide range of issues and support for that community that it's servicing. So that makes it very difficult as we kind of try and integrate with prehospital care around the country.

-Thanks, Jason.

Jim?

-I think as the conversation talks about tiers and different resources, but just as I think putting it in the perspective of being a patient advocate, we need to think about equity and making sure that we not only look at costs, but how we can assure that we are able to deliver the needed resources in all the markets in communities that we serve. So that is certainly something that this Committee has to keep in mind as well. Whether it's a tiered model or a varying degree model, having some way to be able to assure that those various

tiers are connected in a way that there is appropriate service being provided in the regions that need it. So, I think that's something that we just have to keep in mind when we think about the tiers. Certainly, reimbursement plays a part, but we also need to think about the needs in identifying where the gaps in our services lie.

-Thanks. Ben.

-Yeah, going back to kind of, you know, where we operate, you know, we're close to half a million square miles, and I would hate to put different air ambulances of different clinical capabilities and who am I going tell that they don't get the highest level of care across the half a million square miles that I'm serving. To me, these are, you know, ICU level care, that is available and oftentimes we are the highest level of care available within 150 miles of these people. So, I would have a tough telling some super rural community, “Sorry, you're only going to get, you know, a lower version, right?” From, from a patient perspective, I just feel like that could be problematic.

-Yeah, I really appreciate the discussion. I'd like to be able to go over to an anonymous question from the public to be able to ask in their question. I'll just repeat it, just in case no one has that window panel up.

It's: who determines the overall quality performance of a program should these different levels be adopted? It seems like a model that could be abused by saying we can do all these things but not well with poor oversight.

Josh, I don't know. Do you have any insight on that or is it in development? Excuse me.

-Yeah, I would say it's in development and these are a lot of this information whether it be GAMUT that looks at some of the data that we have whether it be CAMTS accreditation, whether it be following different standards. I mean, there are metrics in place to ensure that it's not a, you know, I always use the expression putting a lot of ornaments on a dead Christmas tree that looks pretty, but it's not healthy and it doesn't have strong roots. I mean ultimately this whole tiered program would have metrics and objectives and quality that would be that oversight side of it.

As far as the implementation of that, I'm sure there's a lot to be determined still and based on the Committee's recommendation.

-Thanks. And I do think that some of these questions that we're discussing right now is really going to be on why we developed two Subcommittees. The clinical standards committee, we're going to be able to vet that out. That Committee is going to be tasked to be able to do that. So, this is a really good launching pad to be able to talk about that. And

so really excited about that. And I think Kolby, to your point, I think in the chat there, I think, a very good point from that. And those of you can read his discussion there. Any other questions as we're getting close to time?

-Bill?

-Thanks, Jeff and Josh, thanks for bringing up GAMUT. I was there many years ago when the idea of GAMUT was first born, and I think it's been a really good thing for our patients. I do have some concerns about the idea of tying reimbursement to GAMUT performance unless there is significantly greater oversight of how people report their GAMUT performance than currently exists. From what I see, comparing my own program's performance with some of what other people are reporting, I think there's a wide variation in terms of how people are doing that process, that would need to be tightened up quite a bit if reimbursement were ever to be tied to GAMUT performance. And also there's the idea that in a just culture, reporting is encouraged and tying reimbursement to GAMUT safety performance like sentinel events could disincentivize reporting.

-Yeah, and I'll just respond, Bill. Thank you, Bill. I appreciate that because I think, you know, that the two big challenges are: what would a tiered structure look like? Because ultimately the higher the level of care that we're providing, because there is a variation right, and you know, I can speak a lot, you know, the difference of the programs here is really key to these good conversations, right? In the state of Texas, we have a very difficult area servicing some of our region, especially South Texas. And a lot of it has to do with the reimbursement or the lack thereof. And so, I think providing some type of air medical presence is key. Can we at this time provide, you know, put an H 160 with a physician and two pilots, and I mean you look at the expense associated with some of these platforms, and I think it's cost prohibitive at this time. So for us, a regional approach, you know, I'd love to say that we could do the same thing across the state of Texas, but I think there's going to be some growing pains with that.

And when it comes down to the variables associated with quality, we use GAMUT as an example, but ultimately, you know, we look at the aircraft type, we look at the clinical capability, look at education, the training and who's on the aircraft. I think the idea is to have numerous metrics that are put in, but as far as the oversight and how the Committee decides to move forward with it, I mean, it is no easy task. And I will say that we'd love to help in that implementation or the oversight, but we do look forward to hearing how the Committee moves forward with it.

-Thanks, Josh. Trying to look at our time here to be able to see. It looks like we have about six minutes left to be able to do that. Yeah, left with where we're at. So, I think looking at

some of these specific questions and believe that a lot of these things will be addressed within the Subcommittee.

I think Josh not again to put you on the spot, and I really appreciate you being here, on this, for this, this conversation. There is a question about pediatric specialty care in the tiers is that is that from what I read was that really at the highest level? Is that a correct assumption off your slide deck?

Yeah, it's correct. So, we have not dived deep into pediatric specific, but if you have specialized people providing specialized care in that environment in pediatrics, infants, neonate, NICU patients, those would be a specialty area.

If you don't mind, I'll skip to the next one as well since we're limited on time. And that's kind of the goal. It looks like the attendee had noted if there's a way to tie the quality and safe reporting.

Kind of what we do for our inpatient system, our acute care centers, where we have that as a level 1, 2 and 3. I think that's kind of the goal that to have if we're a level one, can we have level ones all over the place? We'd love to have level one trauma centers across the state, in every city, but that's just not a possible scenario. And so, providing the resources from an air medical side that's most applicable based on supply, demand, cost, reimbursement, multiple things, I think it's kind of the goal for this, so, thank you for that.

-Okay, it looks like we're at four minutes. I'd like to be able to see if there are any other questions for the panelists.

There was a I think maybe Jason, if you saw that, and Jana, if you saw that the question from the FAA and if there's anything you can address on that, Jason, if you saw that question from Katherine Wright?

-I mean, I think it's a great question around infrastructure and the role it plays. It certainly is a challenge in terms of our access to be able to move patients in a timely fashion. I think that one of the challenges we face and this will certainly come up in our discussion on the Flight Safety Subcommittee, is the different ages of the formal landing areas that are available in the country and at hospitals. Combined with the fact that even while we may work to improve those, we still do a lot of operations that are in places that do not have formal landing sites or prepared landing sites. So, on the one hand, I think we will probably talk about what we can do in partnership with the FAA to try and upgrade the infrastructure that exists and then in part there has to be a significant discussion around how we use safety management systems to manage the risk of operating in places that are uncontrolled or unprepared for formal operations.

-Okay, great. Thanks, Jason. Alright, any other questions for our three presenters that we have?

Okay, if there is none, with the time that we have remaining, I'm going to kick us back to our break which I believe is about a 10-minute break or 12 minutes. T- minus 12 minutes right now, and we can go ahead and take our break from there. I appreciate everyone. Great discussion from the Committee members and this is really exciting. So, thank you.

BREAK 12 Minutes

- Hope you enjoyed your break, and Jeff will turn it back over to you.

-Okay, thank you. So please, welcome our next presenter, Nolan Crawford. Nolan Crawford is an aviation safety inspector (ASI) assigned to air transportation division 135 flight operations section AS220. He is a retired army master aviator. Nolan has over 35 years of aviation experience both military and civilian that spans air traffic control, helicopters, and airplanes. He holds an airline transport certificate and flight instructor certificate for helicopter and airplanes.

Welcome, Nolan.

-Hey, good morning, and thank you for having the Federal Aviation Administration to be part of this important event and the ability to present on the federal aviation regulations with a focus on the air ambulance regulations.

The FAA takes operational safety seriously. And hopefully through this presentation, we can discuss some of our methodology on regulating training best practices to enhance operational safety not only for our crews and our operators, but also for our patients who happen to be on board these aircraft.

Through this presentation, I'll try to show the regulatory framework, the method that we authorize these operators, and the current guidance that we use in air ambulance operations. Next slide, please.

So as many of us know, the air ambulance world actually started back in World War I using biplanes to move the sick and injured from the front lines back to medical care. Since that time frame though, the transportation of patients needing medical care or medical attention has expanded into a significant industry carrying thousands of patients each year. The air ambulance industry continues to expand in response to the dynamic growth of this industry. The Federal Aviation Administration has issued federal aviation regulations,

orders, and advisory circulars that help us provide the information, rules, and guidance to the air ambulance community.

The overall goal is safety for our pilots and for our patients onboard those aircraft. Next slide, please.

Some of the critical definitions for us to understand is an air ambulance aircraft is an aircraft that is equipped with medical equipment appropriate for the type of care needed for the patients.

An air ambulance aircraft is an aircraft equipped with medical equipment appropriate for the type of care for the patients. As you can see by this slide, you see hospital-to-hospital services scene-to-hospital. The infrastructure of a hospital is very important and to the safety of our crews as well as to our patient care. Next slide, please.

So, a couple more definitions that we'll talk about here is air ambulance aircraft, air ambulance operations, and medical crew member. It's very important to understand the meaning of these as they have specific meanings in the regulatory and guided structure we use within the FAA.

An air ambulance aircraft is an aircraft used for air ambulance operation. The aircraft must be equipped with medical equipment appropriate for the care for the patient and safety. The aircraft does not need to be exclusively an air ambulance aircraft, nor does the equipment need to be permanently installed.

An air ambulance operation is an air transportation of a person with health conditions that requires medical personnel as determined by the healthcare provider. It's holding out to the public, as willing to provide air transportation to a person with a health condition that requires medical personnel as determined by the healthcare provider, but not limited to the advertisement, the solicitation, the association with hospitals, or medical care personnel, the use of an air ambulance aircraft, whether that be fixed-wing or whether that be a helicopter.

The last one we'll talk about here is the medical crew member is a person with medical training, who is assigned to provide medical care and other crew member duties are related to the aviation operation in flight. Next slide please.

So about 70% of our air ambulance aircraft and operations in the United States these days is done in a rotorcraft. These are primarily used for scene calls, short-distance, hospital-to-hospital transportation as some of the other presenters have already talked about.

Rotorcraft air ambulances will be a part of our focus today, but not our only focus.

A big distinction between the fixed-wing and rotorcraft operations is rotorcraft is not always under the direction of air traffic control, where most of your fixed-wing air ambulance aircraft typically operate in connection with an air traffic service. Next slide, please.

The remaining percent, or 30% of the air ambulance operations within the United States, are fixed-wing aircraft. Fixed-wing aircraft are predominantly used for long distance, hospital-to-hospital transportation or airport-to-airport as we talk about sometimes.

As you know, these aircraft typically operate in the IFR, under the instrument flight rules or IFR, within the NAS (National Airspace System) where again that does not necessarily happen in the helicopter side.

Given the nature of the medical services provided by the fixed-wing air ambulances, they are generally operated under IFR, they are more structured in that sense, and they encounter fewer regulatory ambiguities than our rotorcraft counterparts.

Some of the fixed-wing operations generally do not happen in an emergency environment. These operations tend to be less emotional for the crew and for the medical personnel than in the rotorcraft environment when that aircraft maybe going to a scene call or, you know, at night under night vision goggles, things of that nature. Next slide, please.

The air transportation division AFS 200, more specifically the 135 ops section, is the section that that is responsible for the regulation and policy recommendations, governing certification and operational aspects of the air carrier, and the commercial operators, or for this term for this briefing, for the air ambulance community. The 135 operations section manages air ambulances under Part 135, and we have special rules that do that. These rules require a higher level of pilot training, certification, maintenance procedures, safety and rules than the pilots who may just want to go out and fly their family or friends under part 91 or the general operating flight rules.

We have specific rules and operational specifications that we'll talk about in this briefing that regulate and authorize air ambulances.

The flight operation section develops and maintains these operational specifications along with the policy and guidance that are associated with them, and not only do we look at the air ambulance side, but we look at a wide range and types of operations conducted under part 135 air ambulance just being one of those types of operations. Next slide.

So, our regulatory structure, we start with statutes. In many cases, the FAA works under a structure from our legislators through statutes. They are sent down to the FAA, and we're given guidance on what we have to do, and we have to follow those statutes and sometimes those statutes push us into either the regulation world, the guidance world, or things that we have to put out to our own folks and orders. One way to think of this is, safety begins at the top. We have statutes also known as acts, which are laws passed by the legislators. These sometimes set the framework for the FAA's policies and guidance.

The Federal Aviation Regulations are rules prescribed by the FAA governing all aviation activities. Whether it be the Part 91 that had previously discussed the general operating and flight rules or the 135 operating rules which deals with commuter and on-demand operations and governing person on board those aircraft.

The last things I put on there because I think it's important for this Committee to understand is, we use a variety of aircraft, whether it be fixed-wing aircraft or whether it be rotorcraft aircraft and potentially in the future, powered lift aircraft. So, some of the rules that don't necessarily affect the individual pilot or the individual operator are the rules certifying the aircraft which we use. Each one of those rules has its own set of safety things that the aircraft must meet whether it be normal category or transport category. Next slide, please.

So, what I would like to do at this point is, let's focus on that 70% initially and then we can come back to the fixed-wing side of it. So, 70% falls under the Part 135 or sub Part L of 135 regulations for helicopter or ambulance. The applicability as you can see in this slide, the final rule addresses air ambulance, commercial helicopters, and general aviation helicopters. The rule was created because of an increase in fatalities that was happening back in 2008-2009 timeframe. The rule actually became effective in 2014. With the final rule, we had an increase in weather minimums for all general aviation helicopters. Many of these requirements were addressed in the National Transportation Safety Board recommendations, and the rules were intended to provide the certificate holder and pilots with additional tools and procedures that will aid in preventing accidents, making it safer for our pilots, our operators, and our patients on board. Again, that rule became effective in April of 2014. Next slide, please.

So, the orders that we use for our aviation safety inspectors and that our operators fall under, we authorize helicopter air ambulance operations under A021, and we authorize air ambulance operations and airplanes under A024. Again, guidance for our FAA inspectors, which is also valuable for our operators, and they have access to it, is Volume 3, Chapter 18, Section 7, which is helicopter terminal instrument procedures in airport authorizations and limitations. Next slide, please.

Operational safety. The FAA orders and notices are issued by the FAA as guidance material for our personnel for aviation safety inspectors, such as me. While the aviation safety inspectors are the primary focus for orders, we then step over to the advisory circulars which their primary focus is on industry. The advisory circular, we use, to officially recognize an acceptable method but not the only method of accomplishing and showing compliance with airworthiness regulations, as well as operational regulations. Advisory circulars may also contain explanation, clarifications, best practices, and other information to use for use within the aviation community, that could enhance safety. Couple of the other things you see on here, we talked about infrastructure. There was a question in the last period about it. The AC 150/5390-2D is the heliport design guide. We use that when we teach our aviation safety inspectors what they need to look at when they go out and look at a heliport. Just as a plug for anybody that's looking for more information on that, Transportation Safety Institute is the organization that teaches this course, and we're actually starting to open that course up more and more to industry. So, if you're interested in getting more information on that as a committee and what we're doing with that, I'll be happy to talk with you offline. Some of the other things that you see on the slide here, the instrument flying handbook, the helicopter instrument flying handbooks, and a couple of the ways we get information out on safety events are INFO, information for operators, or SAFOs, safety alerts for operators. We can use that if we find a problem going on that we need to get a safety notice out to someone. That's two of our techniques and two of our documents that we can utilize. Next slide, please.

-Okay, Nolan, it looks like we're about we're done with timing. You want to just quickly wrap us up and then we can move on?

-I've got about two slides I'd like to hit for the Committee if possible. I think it'll bring it home and then we can be done.

-Okay.

-So, the slide here I would like to bring up and show you the volume of air ambulance operations across the nation. We flew last year, 2023, approximately 528,000 flight hours in air ambulance operations. With that, we flew about 385,000 patients. That basically means that we're flying a patient about every 90 seconds. That gives you an opportunity of about one in 1,000 to be a patient on board one of these aircraft.

So, in saying that that's why this is so important that we get it right through the Committee, and this document right here is actually posted on the AFS 200 website. So, if you would like to see that information, Congress mandated us to point that out, I'll be happy to break that down.

And the next slide, I'll close it out with that. This is some of our helicopter operation industry partners that I would like to throw a plug in for this. These folks can give this Committee a lot of great background, whether it's the Vertical Aviation International or VAI, the Air Medical Operators Association (AMOA), the Association for Air Medical Services (AAMS), and the United States Helicopter Safety Team (USHST). With that, I'll be happy to answer any questions on this presentation.

-Thanks, Nolan. I really appreciate that overview. That was really, really good. So just going back to, just a little bit of a housekeeping, and we will answer questions after our last speaker here.

So, what I'd like to be able to do is make a note that questions entered the into the Q&A box will be answered following the meeting and added to a summary report that will be posted on the CMS AAQPS Committee website. The Advisory Committee on Air Ambulance Quality and Patient Safety, just since I did the acronym, and we all know that we love our acronyms.

Also note that members of the public may submit written comments for consideration by the Committee at any time via the AAQPS@cms.hhs.gov. That's a way to be able to do that. So, everyone has that website.

I'd like to be able to move on to our next, speaker, and again, thanks, Nolan for that high overview. I really appreciate that. Next, I'd like to be able to move on to Joseph House.

Joe House is the state EMS Director for Kansas and the President of the National EMS of State EMS officials, NASEMSO, he serves for the Kansas Emergency Medical Services Board. Initially hired as the Deputy Director of the State EMS Office from 2011 to 2014 before being appointed as the board's Executive Director and Chief Administrative Officer of the State EMS Office from 2014 to present. Joe has been active in EMS since 1997 enjoying, maintaining, and utilizing his current certification of a paramedic for the past 22 years.

Thanks, Joe, for joining us.

-Chairman Richey, thank you very much for that wonderful introduction. Members of the Committee, again, many of you know me, and that was a great introduction. Kind of an overview of where I was at and who I am. We are the State EMS Office in Kansas. We are also known as kind of the regulator of all things EMS related in Kansas. More importantly, who I'm representing today, I am the president of the National Association of State EMS Officials or NASEMSO.

Great to hear the plug on all the acronyms that I'm sure you're keeping track of as we're going through here. NASEMSO is an organization I currently have the privilege to lead representing not only my office in Kansas but also the State EMS Office in each of our 50 states and Commonwealths, the District of Columbia, as well as five of our recognized US territories.

So, our 56 entities united is what makes NASEMSO. We are the collective voice of the nation's EMS systems. So you've heard the old adage, no doubt about it, if you've seen one EMS office, you've seen exactly one EMS office, but our organization disagrees.

And we're trying to change that adage. So, we may have different structures within our specific jurisdictions, but each EMS office has the same mission.

Our mission is to protect the public through the effective regulations and oversight of our entire industry. So, what we've termed the EMS system, all components of it. As you're well aware, air ambulance services and air ambulances themselves are necessary components of each of those EMS systems with the patient care components of their operations regulated by our offices in our respective jurisdictions. So that's a responsibility that our states don't take lightly.

In some of our systems, air ambulances are the only means of the effective and timely delivery of critically ill individuals to hospital capable of treating a patient. In some of our systems, air ambulances are core components of the 911 response and others are predominantly only needed for tertiary care and interfacility transport and in some they're the only means of accessing a patient. So, analysis of the system, identifying the system's needs, are how we develop our plans to enable that effective and coordinated response for the patient. So, to minimize or reduce risk, morbidity, and mortality, all of our member offices strive to remain patient-centric within their regulatory functions.

So, as you're well aware, this Committee charged with recommendations for the qualifications of those different clinical capability levels and the tiering of such levels, it's no easy task. Additionally, you're charged with recommendations for the clinical triage criteria for air ambulances.

Again, from the voice of experience, it is not an easy task. We believe these two charges are instrumental in the development of a third charge of recommendations for patient safety and quality standards.

So, but all is not lost. We want to assist you in making this a little easier. So, our member offices hold ideas. We hold suggestions for these components from the regulatory and the regulator perspective. So, from the voices of experience, the lessons we've learned along

the way. And I've been asked to share six of those items, suggestions, and ideas with you for your consideration when developing your recommendations to Congress.

So just kick off with that charge on the qualifications and the different clinical capability levels. So, sure we have basic life support, BLS, we have advanced life support, ALS, and then we have specialty care transport, SCT, in the ground world, and we would argue these are easily migrated across the air ambulance industry as well. However, most of our air ambulance services operate with more than just EMS providers on the healthcare team. So, examples such as the paramedic-nurse combination or a nurse-nurse combination, but physicians, respiratory therapists, physician assistants, nurse practitioners are also all personnel who will be part of the very appropriate clinical crew team. This multidisciplinary approach enables the capability to adjust the clinical crew to match the clinical needs of the patient. It's this flexibility that is the gold standard. It's that flexibility that has to continue to exist.

So, our first overarching suggestion to this Committee and your recommendations, please hold the ability to achieve this gold standard to maintain this flexibility across all tiers. Please keep as much of this flexibility intact that's humanly possible.

Starting with that in mind and within the same vein, our next suggestions continue with the BLS, the ALS, and the special care tiers, but strongly consider the inclusion or carving out of a critical care tier. Although critical care may be a portion of specialty care, we believe there are enough differences between the two to consider them as two completely separate tiers.

Critical care capabilities should include providers who are required to have regular maintenance, continued verification of high risk-low volume skills and procedures. Kind of starts to blend into a little bit of a quality standard there. So that ensuring these skills and procedures with it, which if they're not performed timely or performed correctly, have a high probability of leading to an increased morbidity or mortality of the patient. Ensuring those skills are maintained to the point of extreme precision and extreme proficiency is necessary. Ensuring patients presenting in critical conditions have the providers necessary to mitigate the immediate threat, as well as those threats likely to occur during contact and/or transport, and we believe it's that component that actually does carve out the critical care aspect of it.

Differing from critical care though, specialty care may be more along the lines of including a provider who has the clinical knowledge and expertise to handle a specific medical condition on perhaps a less acute basis. So, thinking along lines of ongoing maintenance or overcoming of an acute exacerbation of a specific illness or injury of a patient with an underlying known medical condition, but presenting in a less critical state where that

underlying medical condition and the differences in clinical care being presented to them are going to have to be addressed.

So numerous transports by our air medical entities across the country are not necessarily because of an acute critical state, but rather because the patient presents in a very stable but complex medical state due to those competing medical conditions. That is why NASEMSO believes specialty care and critical care should and can exist as two completely separate tiers.

Switching gears just a little bit to your charge of quality standards and clinical triage criteria for air ambulances. So as the entities charged with establishing and forcing systems designed to maintain quality, many of our represented offices have looked to develop a scoring method or some sort of system by which we can quantify the severity of illness or injury, by which we can quantify the need for quicker transport or reduced out of hospital time, by which we can assess the quality of the care being provided to the patient.

So currently most of your air ambulance industry perform utilization reviews to ensure the appropriateness of this scarce resource and are mandated to perform quality assurance to ensure the appropriate care for the patient was delivered and that's done via state regulation. However, we continually wrestle with this thought of, if we were to have air ambulances take solely patients who meet specific triage criteria for criticality, we would immediately see the shuttering of numerous organizations and aircraft, making these already scarce resources even more scarce. Which actually engages a very unintended consequence of not having the resources available when it truly is needed. So there's a very, very delicate balance, which is really been the largest obstacle to a lot of our state offices and moving through this, which leads to our next suggestion.

Please, within your recommendations, be mindful of this delicate balance with any developed clinical triage criteria and any developed quality standard. It is truly a walk across a tight rope where the failure to maintain balance has critical consequences.

So many of our member offices have trialed or researched a scoring method to determine the level of care necessary for the presenting patient. So, this practice proves to be a tremendous tool for the determination of appropriate utilization, however, the pitfall of most of those current scoring methods comes down to provider preference and or provider bias interjecting subjectivity. So, by provider we mean the attending clinician, whether physician, a physician assistant, nurse practitioner, any other healthcare provider, but in our opinion that ideal scoring method or triage criteria should be completely objective, based upon the presentation of the patient. So, unfortunately some of the current bias is also interjected from current reimbursement constraints such as a patient who may be completely stable, but due to a lack of ground resources is taken by an air resource.

Later today, you're also going to hear more about the National EMS Information System or NEMSIS from Eric Cheney and Dr. Clay Mann. I don't want to steal any of their thunder, but Committee members I will simply say NEMIS has the capability of being the key to unlocking a successful scoring method. If NEMSIS data could be linked to patient outcome data, to hospital outcome data, analysis could easily be performed to begin to identify the metrics indicating and defining triage levels for the more appropriate usage of our ambulance services. So, allowing utilization review to continue to exist but to exist to identify and address the outliers, acting as a safety net within the system as opposed to being the primary catchment. So, you heard me saying NEMSIS data could be linked, but it's much, much more. It is being linked in some of our jurisdictions, but only for a total of about 1- 2% of all that's out there. We can do better. We have to do better.

So, we have three suggestions within this component. First seems rather obvious, but the obvious sometimes helps us place things into just a great frame of reference.

So, Committee members, let good suffice. Perfect should not be your goal. Find something which is good and can be tweaked over time and then establish a system to review and tweak this criteria and these quality standards on a regular and ongoing basis. Let it be living, breathing, evolving as medicine evolves, as industry trends change, as technology enters into the mix. So, this voice of regulatory experience has seen numerous good and great ideas get significantly delayed or just flat discarded because we wanted to continue to strive for perfection on the first iteration. Resist the urge. Let goods suffice. Build that or recommend that a strong system of review and adjustments be built.

Our second suggestion: make the criteria objective. Objective criteria are a consistent approach across any jurisdiction boundary and objective criteria mean a consistent approach to appropriate and evidence-based care. So, this is true to your quality standards as well as clinical triage criteria. Limit inputs related to subjectivity as subjectivity is a cancer which will quickly devalue and devolve any tool, any criteria, and any standard you recommend. Subjectivity unintentionally introduces doubt and skepticism. Objective criteria are consistent, measurable, and reinforce your goals.

Our third suggestion, linkage between NEMSIS data and outcome data must occur. You heard me say just a few seconds ago, 1- 2% of this data is currently linked, but we must be better. Interoperability between data systems should be elementary at this point. Your only method of measuring the success of clinical triage criteria is this linkage. The only way being able to assess achievement with standards is to be able to measure and to have the capability to measure on an aggregated basis. When this linkage occurs, a complete assessment of the system occurs. Effective patient care can be measured, scoring tools can be modeled and tested retrospectively, quality can be measured and reported, and

you'll have a means by which to develop strong and meaningful clinical triage criteria and quality standards, which are patient centric. The patterns will quite literally jump off the page at you with key objective clinical triage criteria elements being identified. Data is needed. This linkage is critical to ongoing success.

On behalf of our entire membership, I do appreciate the time and opportunity to present the views and opinions and suggestions from NASEMSO, the voice of the Nation's EMS systems, and your regulators of EMS in its entirety.

To just to quickly revisit, summarize our six suggestions.
One: we ask you to ensure your recommendations upon different clinical capability levels and tiers maintain the existing flexibility of staffing an air ambulance to be commensurate to the patient's needs.

Two: Please pattern your recommended tiers to be similar to the ground ambulance side, but in doing so to strongly consider the creation of a critical care tier separate from the existing specialty care tier.

Three: Please be mindful and cognizant of the delicate existing balance related to quality measurement, triage standards, and the continued existence of those necessary resources.

Four: We suggest a recommendation encouraging and/or mandating linkage between patient outcome databases and the NEMSIS database.

Five: Strive to make the clinical triage criteria as objective as possible, making every effort to eliminate or dismiss any type of subjective criteria.

And the final one, number six, maybe the most important: Let good suffice for the clinical triage criteria and for the quality standards but do strongly consider building a system to allow them to be analyzed, adjusted, and perfected over time.

NASEMSO stands ready to support you in this endeavor. I stand ready to assist you with your tasks at hand. You guys are a tremendous group of individuals representing all aspects of the air industry, and I look forward to our continued partnership. More than happy to continue the conversation, more than happy to answer any questions you may have at the appropriate time, to be a sounding board for potential ideas either in this meeting or later, and then to assist this Committee with your inevitable success. So, we are the experts when it comes to regulation of the EMS system. Please use us as you deemed fit, and Mr. Chair, at your discretion, more than happy to go to questions now or just wait until your discussion at the end.

-Yeah, thanks Joe. Yeah, what we'll do is that we'll have the discussion at the end so if you can just stay on for the rest of the next speaker and then we'll go to you for further questions that might arise. So, thanks for your presentation.

-Sounds perfect. Thank you.

-Alrighty, so next up, I would like to be able to move to Dr. Ron Klein. Dr. Klein is a board-certified pediatric hematologist oncologist, and the Chief Medical Officer of the Quality Measurement and Value-Based Incentives Group (QMVIG) in the Center for Clinical Standards and Quality (CCSQ) of the Centers for Medicare & Medicaid Services (CMS). QMVIG is responsible for the development, evaluation, implementation, and support for quality measurement programs across the entire federally funded healthcare continuum. This includes Medicare's Quality Payment Program and the Inpatient and Outpatient Quality Reporting Programs. These innovative programs work to improve healthcare quality for all Americans. Dr. Ron Kline.

-Yeah, thank you very much. Good morning, everyone. It's a pleasure to be here. I know how hard people have worked to get the meetings off the ground, and so I'm very pleased to be able to be part of the first meeting.

I'm giving this talk, basically what my understanding is that most people on this call are not familiar with quality measurement in medicine and so that's the basis of this brief talk. So that's not the case, I apologize if you're hearing things that you already know. Next slide, please.

So, the first slide and you may get this as you start to develop quality measures in medical air transport. I don't think we get to so much in CMS, but the question is sort of a justification for our existence. Which is why are you even measuring quality in the healthcare space?

And what I would like to say is that every successful organization measures the quality and safety of its products or services if it's going to remain successful. We know that retail enterprises measure the quality of the products they purchase from manufacturers to ensure customer satisfaction. And we know if you've bought anything on Amazon or looked at reviews or for a hotel before a trip, you know that the customers comment and applauded their products and the services that they purchase.

So, measuring quality is not really a great step forward, it's sort of a part of our daily lives, and so healthcare is no different. CMS is a payer of healthcare services. If we include Medicare, Medicaid, and health insurance exchange subsidies, we're spending

approximately a trillion dollars a year on this. And Americans are consumers of healthcare services. So, it's certainly within our purview to measure quality, and for healthcare for Americans. Next slide, please.

So why does CMS measure quality, you know, beyond why we should. First, you can't improve what you can't measure. If you don't have metrics to know how people are doing, you can't improve it. If you're trying to improve performance, you have to have performance metrics. It's a method to understand performance. It's a key part of ongoing continuous quality improvement and PDSA (Plan, Do, Study, Act) cycles, and we link it to payment programs and then the final point there I put that in orange is that it's consumer awareness and action spurs provider improvement. So, one of the interesting things I worked previously on, the oncology care model and the innovation center, is that how practices are perceived publicly, how hospitals are perceived publicly, how physicians are perceived within their own practice compared to other physicians will quite often spur more improvement than any kind of financial incentive you can create. So, being able to publicly share how different health facilities are doing is actually a great spur to improvement.

Currently we have approximately 500 measures in active use. Many, many organizations, such as hospitals have to comply with more than the CMS measures. They have separate individual measures that come from commercial health insurance companies. One of the things we're working on is trying to align all these measures to try to decrease clinician burden. And I think the last point there that's underscored, and I'll talk about this more later, is that we're moving towards more of a digital outcome and patient reported measure.

Patient reported measures because physicians find that even though we think we're listening to our patients, we sometimes are not hearing and so having patients tell us how they're doing is very, very important. And a slide that I'll get to a little bit later is if we're trying to decrease clinician burden, then having measures that are abstracted from the EHR (Electronic Health Record) without additional administrative burden, really decreases that burden. So, we're working very hard to move to digital measures. Next slide.

So, what are the CMS Quality levers? Obviously, you know, there's, payment policy. So how we choose how much we pay for various different things is important. We have the conditions of our participation, which basically we refer to as a nuclear option, which basically says these are the conditions under which you may participate in the Medicare program if you don't comply with these conditions, then you can't receive Medicare payments. And one of the interesting historical facts is that 1964 and 1966, hospitals in the United States were desegregated partially as a result of 1964 Civil Rights Act, but also because Medicare (via the Medicare Act) simply said if you have segregated hospitals, you can't participate in our Medicare program. So that probably did more to desegregate hospitals than anything else U.S. government did, and so that's, a very, very important lever.

We have surveying and certification programs, we have our quality improvement organization network, we have our coverage and analysis group, which basically says what technology, what medicines we're going to cover. We have what's called CED, which is coverage with evidence development, which deals with, trying to pay for new technologies that might be considered investigational if they're done under the context of a clinical trial. So, in a sense, we're saying this is not quite standard of care, but it's close, and we'll pay for it as long as you're willing to, you know, make this part of the clinical trial so we can capture the data.

We work with clinicians. We have quality measures which I'm going to speak to. We have value-based programs which we'll come to on the next slide, and it's worth saying that about half of our programs are payment programs so, they actually affect payment, and the other half are basically what we call pay for reporting. So, there is no payment based on how well you're doing on a measure except that those measure how you're doing, even though they're not based on payment, are publicly reported, which again I'll get to in a couple of slides, and we work very, very closely with stakeholders to try to help them improve. Next slide.

So, this is for those of you who aren't familiar with quality measurement. This is the most important slide I'm going to show today because this is really going to create the intellectual framework for how you might think of quality measures. This comes from Avedis Donabedian, who published in I think probably in the late 1950s- early 1960s. The JAMA citation from 1986 was a review of his work that he wrote. And this is how the medical community tends to think about quality measures and how you might think about quality measures as you think about measuring quality within your world.

The first are structural measures, and they refer to the attributes of the settings in which care is provided. This includes material and human resources, organizational structure. I'll get back to air transport a bit later, but in terms of our world, for instance, I'm a pediatric oncologist, you have a pediatric ICU. Well, you're going to provide critical care to sick children. Do you have a designated physical area for those kids? Do you have a board-certified pediatric intensivist? Do you have certified, you know, critical care nurses, pediatric clinical care nurses? So, those are the structural measures, those are the attributes of which care is provided.

The next one are process measures. So, what is actually done in providing and receiving care? It includes both patient and provider activities and making a diagnosis and recommending or implementing treatment. So, if we want to improve care for diabetes, we should ask the question, "Are you measuring hemoglobin A1C?" and I presume most folks

are medically knowledgeable here, but if you're not the hemoglobin A1C is for a measure basically your control of your diabetes.

So, if you're going to make diabetes better, first you have to ask the question, “Are you at least measuring those things?” And those are called process measures.

And then the last one, and these are sort of our gold standard, our outcome measures, which is the effect of the care on a health status of patients and populations. Improvements in patient behavior and satisfaction with care are included in the definition of health status. And the reason I say the outcomes are our gold standard and that's probably, you know, a statement I think most of us agree with, that medicine is complicated enough and nuanced enough, that often times we have these discussions that basically say, “It doesn't matter what I did or who's there in my care setting, it's how did my patients do?” And so that's really the ultimate, you know, we want patients to do well no matter how you get there. So the structural measures, the process measures, are surrogate measures for how we get good outcomes for patients. And then the problem with outcome measures and the previous speaker spoke to this a bit, is that if you're going to have outcome measures, you're going to need to risk adjust. So, people are going to tell you, various entities will tell you, well, my patients are different than this person or this entity because my patients are sicker or we're doing this, we're in a rural area, or we're in an urban area or a whole variety of different things.

So, if you're going to have outcome measures, then you very, very rapidly get into this world of risk adjustment, which basically means you have to have some agreed-upon method for saying that some patients are sicker than others, and how you're going to take care of that. Next slide please.

And this is just a quick version of the quality measures and quality programs that CMS has and quality payment in their quality programs.

The red fonts denote pay for performance. This is where money is actually tied to how you do and the others the in black font are pay for reporting programs. So again, you get the full amount if you pay for reporting, but we don't pay you based on your outcomes, although those are publicly reported due to various different systems. And you'll notice that roughly half of our programs are pay for performance, half are pay for reporting, and there are a lot of programs and a lot of these are statutorily mandated. So, the things that are pay for performance and pay for reporting, a lot of times, our ability to either consolidate these programs or change them from one to the other is affected by law, so we're limited to what we can do. Next slide.

We talked about having pay for reporting programs and how payment is not changed based on how you do, but they are publicly reported. Most of you may have heard of the Stars programs, which, you know, formerly known as the Care Compare Programs. We have them for a variety of different things. We have them for clinicians. We have them for home health. We have them for Home Health CAHPS (Consumer Assessment of Healthcare Providers and Systems), which is a patient experience survey program. We have them for hospice, dialysis, hospital and nursing homes. So, if you are looking to interact with any of these facilities, you are a family member, you can go to the Medicare site, the CMS site, and see the Star ratings for the facility you're considering or the physician you're considering. And, as I said before, although there's not really money tied to this, I will tell you that people pay very close attention to their Star rating systems because how they present themselves the world. And so, Star ratings do affect performance, and people do pay attention to them. So, you can move the needle with the Star ratings, the Care Compare Programs. Next slide.

And this is just a sense, you know, as a government entity, we obviously have to have a public, open system for how we consider measures. This is an example of what we do. And from January to May of this year, we had measures submitted for consideration by what we call the merit program. So, anyone can submit a quality measure to CMS for consideration. From June to November, the measure is reviewed within the executive branch, and we decide which measures are important, quality measures that we want to move forward. And we generate what's called a MUC list, which is measures under consideration, and that is published no later than December first of any given year. And so, we just published our MUC list, probably a week or two ago that lists the measures that we're going to move forward for consideration. And then in January, and then those are publicly reviewed at what we call the PRMR (Pre-Rulemaking Measure Review) process, pre-rulemaking measure review, and then we have public meetings in January.

Three different committees review different measures. There's post-acute care, there's hospital, there are clinician committees, and we review those measures publicly and gather comment for what people think of those measures, what their weaknesses are, what their strengths are, what people think we should go forward with and what we shouldn't. In fairness, I should say that we obviously listen very closely to what those committees tell us, but we're not obligated to abide by their recommendations.

Then we've put those, if we're going to go forward with any of those in rules, we put them in the rules which will get published throughout 2025 for either fiscal year or calendar year 2026. So sometimes people ask why it takes so long to develop the quality measure. Sometimes it's the development of the testing, which takes a long time, but it's also a public process to make sure that everyone has the ability to give us their input. Next slide.

And then this is what I alluded to before, which was, how do we measure quality without burdening clinicians with constantly filling out records and charts and administrative data? How do we do that? The way we do that is through digital transformation moving our measures towards a digital strategy. There are challenges. We have to agree on common metrics and data elements. How do we define blood pressure? There are many different ways to report it. How do we define various laboratory values? Units.

So, it seems like it should be simple, but it's actually quite complicated and time consuming and expensive. We have FHIR which is fast healthcare interoperability resources which is the next standard for digital measures and how do we move the world, the US healthcare system across to implement FHIR, which will give us better ability to measure quality. And again, as I say, how do we take existing measures, and put them into digital forms. And then, the goals for FHIR implementation, we work with, the Assistant Secretary for Technology, ASTP, which used to be the Office of the National Coordinator in terms of trying to move towards EHR standards. There's something which is USCDI, which is US Core Data for Interoperability which is trying to get those metrics together. And then there are things called USCDI Plus, which are sort of subsets of those, not quite, but sort of slightly different versions of USCDI that focus on different things, quality measurement, cancer, behavioral health, public health, etc. And so those are all the places that were working. Next slide.

And this is just if you look very quickly at this is from JAMA in 2023. This is from Johns Hopkins. If you look at the third row, the electronic measures, you will see that when Johns Hopkins looked at what they were doing, the person-hours per metric per year, so the third column there, you see the number 40 versus 691 and 836 for claims-based or chart-abstracted measures. So, this is just objective data that basically shows that if you can move to digital measure, you decrease clinician burden, facility burden. Next slide.

We find that in Medicare, patient safety is an issue. Twenty-five percent of Medicare beneficiaries experienced harm. This has been true of several different OIG [Office of Inspector General] reports, and that we're focusing on this as an important measure. Forty-three percent of those harms were deemed to be preventable. Next slide.

Let's go past this, since I'm running our time. And pass this one and the next one, I think. Next one. One more. Sorry, too much to say.

So, hopefully you guys be kind enough to give me an extra minute or two to discuss this. This is relevant to your work. How would you think about air ambulance transport quality measurement?

The first would be a structural measure. You have to ensure that all necessary equipment and properly trained personnel are available during medical air transport. And I believe the previous speaker spoke about that. And you tier this for different intensity and complexity of levels of Medicare and transport.

So, you're doing an air transport, you know, is the right nurse, the right respiratory therapist, the right physician, you know, who's available on that flight? Is the proper equipment available on that flight? Next slide.

Process measures. I don't know your world very well, but what kind of consensus clinical activities exist that the medical air transport community agrees are important for achieving the best outcomes.

If you're transporting a pediatric patient, what do you need to be doing? That could be true of a structural measure as well. Cardiac patient, a septic patient, a trauma patient. So, what are the process measures? What are the things you need to do that you can all agree on are important that, that should be done for to ensure optimal outcome.

And then the final slide is our outcome measures. So, what are first steps that you might look at? So again, looking at outcome measures, we know broadly thinking, all-cause mortality during air transport, preventable complications that occur during air transport, and of course, the hard part of all this, right, is that you can't just say, who died and who had a complication. You have to risk adjust this because different air transports will have different levels of risk associated with them. So, you're going to have to risk adjust. So that's going to be the hardest part of any kind of outcome measure.

And then the final slide.

This is from Montana. Beautiful place. I had a chance to do a Locums there a couple of years ago and happy to take questions and participate in the conversation. Thank you.

-Thank you, Dr. Kline. Great, great information. And yes, there's a lot of information to be able to go over, as we've been going through this.

So, I'd like to be able to welcome the entire panel, our entire Committee back for a discussion. We're going to take about 30 minutes here to be able to have that discussion. So, I'll open it up to the Committee for discussion, and questions for the three presenters.

Grace.

-Thanks for the presentations. This is probably a question for Dr. Klein, although it might get into others as well. So, you know, when you're talking about CMS quality metrics, they primarily drive behaviors that are applicable to the Medicare market, a little bit beyond right, but if you're thinking about financial incentives, those are the primary tools. Do we have an overview of how many or like what percent of flights are covered by those quality measures? And I appreciate this is like a very kind of abstract question and so it may not be you, Dr. Klein. And then I'm wondering, Dr. Klein, if you're aware of private payers that have similar incentives on their privately, like on the either fully insured or self-insured business to meet certain quality standards.

-Yeah, I'm sorry. I'm not really familiar with Medicare payment policy around air transport. I don't know if the other folks on the call are, so really can't speak to that or to commercial insurance quality measures.

-Right.

-Yeah, thanks, Jeff. And I think to, Grace's question, one of the challenges in all of this is that the ambulance transport benefit for Medicare was designed around transport. It was never designed around medicine and the purposes which is back when Medicare got formed, people were getting left on the side of the street after having a wallet biopsy. So obviously, Medicare didn't want, you know, our beneficiaries laying on the street. They paid for transport, but they never really paid for medicine, which I think goes into the earlier presentations, that there's variety of pieces. So, as a result, there's never been conditions of participation. There's never been required quality measures for transport, and whether states have them or not is variable at the state level. That's one of the ultimate challenges in looking at this, this was all about transport, it was never about medicine. Whereas we know today, this is about medicine. You know, and the transport is just a mode of how we deliver medicine.

-Dr. Kline, I saw you just came off mute.

-No, I just sparing myself, the embarrassment of talking on mute if you ask me a question later on. So, nothing to say.

-Okay, thanks, Tom. That was something that I was thinking about is the conditions of participation. Dr. Kline, do you have an idea of how this could work for air ambulances on conditions of participation, similar to what the hospitals do?

-Well, I mean, as I said it's our nuclear option. It's sort of, you have to do this, or we won't pay you. So, it really is a very strict standard. I haven't really thought too much about this for

air ambulances other than sort of outlining the structural process and outcome measures. I know there are other folks from CMS on the call and if they want to jump in.

I will just talk a little bit more and say, be very, very thoughtful about conditions of participation because it's basically, it's like an absolute. You're doing this or you're not going to participate in our program. So, we use those very sparingly for issues that we think are of tremendous national importance. And so, really thinking more as you sort of put your toes in the water in this field. Maybe thinking more about quality measures and getting your feet wet there and going forward from there.

-Thank you. What other questions from the panel? Jim?

-I was just going to add, I think this connects with Dr. Hinckley's earlier comments regarding GAMUT into the last statement of dipping our toe in the water. I think this is where whether it's through an expected program or something else that we either further align with accrediting standards or as part of this discussion amongst the panel as a recommendation. I think it's fair, Jeff, for you as the chairman to note that we need to have some type of process to move forward. Where we have recommendations, not only to what the standards the Committee comes up with, but how we measure those, consistently and across our various organizations.

-And I should add really quickly, I just got a text from Dr. Sean Michael who will be your speaker later on today, and he said he will be speaking about conditions of participation. So, you'll have more discussion with that, and David Wright also just put something in chat on that issue.

-Grace.

-This is perhaps maybe a question to all the presenters and all the presenters that are coming, but as we think about, I mean, I'm thinking quite a bit about the financing side. But also, you know, the consumer complaints and the consumer protection side that result when the financing doesn't work out well, because consumers often get in the middle of that whether it's quality or not quality related. If it's possible to have an understanding of the breakdown of flight payments by payor type. I think that would be super helpful as we're thinking about not just quality but most of what happens in quality is like things that they need to get paid for and understanding that I think will be helpful in understanding kind of the bigger picture of the work that we're doing. So, it's a plea for data. Not a question.

-Any others?

- NEMSIS system does track payors, or has the capability of tracking payors, so that is not an unreasonable ask by any stretch and something that we could probably, I can see if I can at least grab our state's data to send to you to give you as an example, we could probably go further than that.

-That'd be great. Thanks.

-Any other questions from the Committee? Dr. Hinckley.

-Thanks to all the presenters. I learned a lot. I wanted to ask Mr. House. Can you flesh out a little bit more what you meant, when you talked about the delicate balance surrounding triage criteria?

-Sure, and thank you for the question. So that delicate balance that we look at is really the fact of if we start mandating certain measures to be achieved, we will eventually, there's that line that gets crossed that could start entering into market focus as opposed to maintaining a patient centric focus. So, if we can maintain with any type of standard that patient centric focus it doesn't cross that line that really starts impacting the fact of business level decisions. So, we know that a couple of measures that we put out initially when we tested actually did cause a reduction of service within our state for certain companies that couldn't meet those standards and then it started being used as a competitive advantage. So, a marketing ploy kind of on the side of things and so it was that tight rope, walking back and forth, between having a measure that was patient centric but that could not be used for nefarious purposes.

-Thank you. I think one other thing that we should keep in mind that perhaps plays into that delicate balance and also relates to market forces is helicopter air ambulance is a pretty low volume endeavor compared to say, working in an emergency department. So, on a typical flight shift, I will care for one patient on average in a 12-hour shift, and it is somewhat difficult for people to maintain really high-level proficiency in a very low volume environment. And the density of air ambulance bases in a given geographical area will impact how high volume or low volume a given pilot, flight nurse, paramedic, or doctor has the opportunity to do their job and care for patients or fly the helicopter. So just worth keeping in mind.

-That's a really good point, Dr. Hinkley. Any other questions before I go to the Q&A pieces to address from the Committee?

Okay, Nolan, I'm going to call on you. There's a question in the Q&A that HA flight hours noted, I contacted the DOT librarian recently and asked what the US Air Ambulance

statistics were for fixed- wing flights and when they came up empty, are fixed-wing results available?

-The answer to that is actually possibly. The reason you have the helicopter air ambulance requirements is Congress mandated that we report that to Congress each year. AO021, the operational specification, requires the helicopter air ambulance operators to report that data to our section, section 135. We have now made that publicly available on the Air Transportation Division page. There is not a direct requirement for that by rule right now, but I possibly can get some of that data to say it will be as accurate as what's posted on the helicopter side, it probably would not be because there's not a mandate for it.

-And that mandate would come from where, Nolan?

-The one on the helicopter air ambulance actually came from Congress. And I don't remember exactly what year that reauthorization bill required that, but it did come out in section 301 that we make it public. In the reauthorization that came out this year, did make under section 301, it made it public for the helicopter air ambulance side and that's the reason it is now posted where it is.

-Okay, great. Thanks. Jason, you have a question?

-An additional comment, Jeff. I think, just for context, on the fixed- wing side it is going to be much more difficult because many of the aircraft that are used for air ambulance on the fixed-wing side do not have to have a dedicated medical configuration and so, they're also used for a lot of other commercial activity, unlike the rotor wing, which are medically configured and dedicated use.

-Thank you. Okay, so moving down to this is a directed back. I agree we should have a means of measuring quality in all aspects of medical transport unless CMS recognizes error medical transport is more than simply a transport benefit. Where is the incentive for quality?

I think this is probably just being worked on, but I kind of leave it to the experts on our Committee or the panel if there's any other comments on that. And maybe it'll be addressed when Sean speaks later this afternoon.

I'm going to take it as we'll wait and see from that standpoint as we're trying to be able to work through this. So, but I do appreciate the comments in the Q&A, from that standpoint, I hope that we have answered, those questions for the group.

One thing I want to do and it looks like we've got about 16 minutes. I do want to have a bit of a go back and I want, from the previous discussion, presentations that we had previously. I want to talk about the patient perspective, and I want to be able to ask the Committee about any questions or thoughts on making sure or discussing the patient's perspective in air ambulance transport.

I'd like to be able to open that up for the group from the previous presentations.

-Tom.

-Yeah, I think that one of the challenges in all of this is that, you know, we've long recognized is that the average patient doesn't really get a choice. They don't get a choice of a carrier, and they don't get a choice of carriage. And so from a patient's perspective, you know, they believe that they're getting the very best that is offered. I think that's and as Dr. Kline had pointed out, people use those Star ratings at hospitals now. I mean, if I'm going to get a surgery, especially an elective surgery, I want to look at that Star rating of a hospital. There is no way to do that currently and I think that's one of the pieces that this Committee is going to have to wrestle with. Is that that there does need to be some much greater transparency in how patients in the public, and I think to, you know, Joe House's presentations, how the state regulators who are protecting the public really have that at their fingertips of how does this all work from a patient's perspective?

-Thanks. Ben.

-Yeah, I'll highlight again that a big part of it, particularly in where my area is, just the access piece, and the highly rural, highly, you know, we in the care that we are there that we can provide is critically important to these communities. So, from a patient perspective, I just think that access piece is really important for us to remember as a Committee, and how do we ensure access as part of this national system.

-Colonel Coffee.

-Yeah, thanks so much. So, I think from the patient's perspective and my son was a consumer of air ambulances and transport. And so I think the challenge that we need to also keep in mind is how we instill the confidence that there's air operability between state and local versus what is at federal and those regulations. And so really keeping in mind of what's the messaging that we put out to really reinstall the confidence that safety is top of mind when we're having to utilize these services.

-Thank you.

-Thank you, Colonel Coffee. You teed me up. I was actually going to say, and I appreciate Tom Judges' comment regarding the challenges related to choice for our patients. I mean, it should not be lost on any of us that the patients typically, whether they're on the side of the road or in an emergency department in extremis, that's typically not the opportunity for them to do a five Star rating comparison and so they're looking at what is the most appropriate, rapidly and most importantly, accessible option. And I think that is where the Committee does have to come to some consensus on how we apply certain things with an expected standard because if we can't make it practical for the patient to have a choice in that urgent moment then to Col. Coffee's point, then we need to make sure that there are requirements and expectations met for both safety and quality of patient care so that regardless of who's coming, they're going to get the right care at the right time.

-Right. Thank you for that. I really appreciate it as wanting to be able to put the patient at the forefront of what we're doing here and for this Committee.

One thing that I want to be able to do. Look, Tom, you, put your hand up. Sorry, I looked at a comment and then I looked up in your hand is up. So, there you go.

-Sorry, I just, one of the other things I think we really have to wrestle with. So in Nolan's presentation and I really appreciate, you know, we started this in 2012 to get this information about rotor wings because we just had no idea what this looked like at all, and it's been a challenge and I'm really glad this is public. But last year there were about 385,000 patients. Previous three years and looking at that same data, it's, you know, 360 - 385,000 patients. When I was president of Air Medical Services (AAMS) in 2002, we estimated there were 400,000 patients being flown by helicopter every year in the United States. So basically the number of patients being flown by helicopter has not changed in over 20 years but the number of helicopters has changed rather dramatically and that has had an effect on, you know, because the operators like, how do we pay for this? How do we do this? So, I think that, you know, when we talk about access, we've added a tremendous amount of resources and a tremendous amount of fixed costs but it really hasn't translated into additional patients. And I think that's the volume and as Bill noted when you have low volumes, it's hard to maintain complexity in high consequence services. That's another piece that I think this Committee is going to have to wrestle with.

-Ben.

-Yeah, I think, one of the things that I thought of as you were talking about, Tom, is, you know, there's fatigue risk management, a safety perspective there as well. So, I know, 20-30 years ago, aircraft were out there doing, you know, five to six flights a day. Crews were running 24-7 and not sleeping and not getting rest and I think there's an impact to the patient there as well. So, I think there's probably some sort of right size there on how many

patients can they transport in a day safely to make sure that that these crews are available and ready to go.

-Jason.

-Yeah, just, following up on that point, something I'm certainly not a clinical expert here, but I think this is something that probably comes up on the patient side. Part of the proliferation of aircraft, if you will, has to do with changes in addressing medical care for the patient around, speed to care. Right, and having reduced transport times to get those people the quality of care that they need and save things like heart tissue and brain tissue and so I, I think, that that's a piece that probably has to come into this discussion as well to understand the correct balance of how we assign importance to those various pieces.

-Jim.

-I would just reiterate Jason's comment, and we all experience this for those that operate these programs. I have high volume locations and then I have lower volume locations and typically the thing that we can't de-conflict is the geography that comes into play with those. In a metro or an urban area, you're going to have higher volumes and in areas where there's less population stating the obvious, you're going to have lower volumes.

The sacrifice that we have to figure out how to avoid is, if you're going to go to the volume argument then how do you overcome the proximity when the patient needs your assistance? And I think that's a challenge that we'll have to navigate through as we talk through this particular area of volumes versus rural population and access. You can't have them both.

-Okay, thank you. Okay, so kind of going back down to some questions here from the Q&A for the last six minutes.

So, one question is can we clarify we were exactly attempted to establish as this Committee and the value that would be truly added? I would caution potential negative consequences. Impacts not only, only related to administrative and capital requirements, but also downstream impacts that could easily evolve into creating new challenges associated with reimbursement.

I can ask that and maybe David can also reply from that side is that really is the two just going back to the original slide and that is our guiding principles and that we want to be able to take a look at patient quality and safety in both the Subcommittees on the clinical side and the Department of Transportation side, those are the areas that we want to be able to do.

And I think it's a very, very good point, but that's going to be a good discussion that I hope to see coming out of those Committees. So, David, anything you want to add to that?

-No, agree and I think you know the final outcome is making recommendations to Congress. And I think that, you know the expansive perspectives reflected on the Committee as well as the Subcommittees is really going to help achieve that goal. So, thanks, Jeff.

-Yeah, I think Kolby's comment there, that I agree and then, the last one, there should be heavy consideration of classifying clinical crew members in such capacity that they also meet a 14-hour duty day as the pilots do. Currently there is no limit. Maybe I can pass that back to Nolan from that side or any of our other expertise on the Committee from the FAA, to comment on that.

-The FAA currently doesn't regulate crew member side in the same manner that we regulate the pilot flight duty times. So with that, it kind of leads me back though to something I think it was Mr. Judge who was saying earlier about the volume of patients, 20 years ago versus now.

One of the things that I think is kind of overlooked sometimes is the volume of locations that we are actually flying out of, and we have over a thousand locations across the United States that we are flying helicopter air ambulances out of today with just over 1,300 aircraft. At those locations, there's only one state in the United States right now that actually does not have at least in 2023, did not have a helicopter air ambulance base in it. I think we're covering the areas and another gentleman spoke about, you know, volumes. Some areas are high, some areas are low in-patient numbers and that makes it difficult to decide where to put them. That makes it difficult for the operators to decide how to staff them, and which does affect the crew rest side, whether you're talking the pilot side or the clinical side. The ultimate goal for the FAA at least is the safety side. Whether that be the pilot within crew rest or whether that be a clinical personal board, doctor, nurse, a paramedic, whatever the case may be, that is providing a valuable role in using the crew resource management side of that. They have to be rested. They have to be a valuable part of that crew, and we got to make sure when we're looking at this, we're not only looking at it from an aviation side but the clinical side and where those two mesh in the middle that mesh should be on the safety side focus in my opinion.

-Thanks, Nolan. Rob?

-Good afternoon, everybody and good morning to those folks west of the east Coast. I think this is a great point that should be discussed and debated within the Committee. I've

thought about the question, the conversation, and some of Nolan's responses. I think one of the questions in my mind is, where is the line between what the regulator requires and what industry can do on their own? For the FAA to require those folks to be considered under those duty time limitations would require a rulemaking on the agencies part to expand the definition of a crew member and then that would work through that process about how we would extend duty time limitations. I think there are other, and some of the other folks have brought it up, I think there are other considerations, that, can be discussed as well.

Those particularly around safety management systems (SMS), and how the air carrier looks at the hazards and risks and the proposed mitigations under their risk under their SMS framework. Recent rulemaking from the FAA, has expanded part five. Applicability to part 135 air carriers although I know a large percentage of our air ambulance operators under part 135 have been complying with our voluntary program for years. I wanted to share the mitigation piece.

Also on the scheduled airline side, we typically have a rule that we apply part 117 around flight and crew member duty limitations and rest rules. These are more of a performance-based rule structure, but air carriers under part 135 can also voluntarily comply with part 117.

So, I think that there's a very fundamental question for this team to evaluate which is, what is the prescriptive role of the regulator versus what is the air carriers responsibility to manage and mitigate risk and where is it appropriate for this segment of the industry for the regulator to be prescriptive versus the air care to be proactive. Over.

-Alright, well, great. Well, thanks. Thanks for that. We were at time, but I wanted for the last person that put a comment in about the patient safety question. We'll get back to that later on this afternoon as we go through that. But I'm going to hand this over to David. I want to thank everyone. This is a really good discussion and we used every single second of it. So, handing it over to David.

-Thank you so much, Jeff. Great job guiding everything through this morning, and we will now take a 45-minute lunch break. So, look forward to seeing you all right around 1:25. Thanks, everyone.

LUNCH BREAK – 45 Minutes

Okay, I think in the interest of time we will reconvene and hope you all had a good lunch break. We'll start the afternoon talking about Flight Safety Data and Best Practices. I'll turn it over to our Chair Jeff Richey again to get us started. Thanks, Jeff.

-Alright, alright, thank you, David. Alright, well, welcome back everyone. Hopefully, you had a good lunch or breakfast for those of us on the West Coast.

So, as a reminder, we want to note that all questions entered in the Q&A box will be answered following the meeting and added to the summary report that will be posted on the CMS AAQPS Committee website that will be entered there. So please refer back to that. So just looking through some of my things here. So, I'd like to be able to welcome our next presenter, Lee Roskop. Lee Roskop is an Aviation Safety Coordinator specializing in rotorcraft linked safety for the FAA Aircraft Certification Service. He joined the FAA in 2009. Prior to the FAA, Lee was an engineering specialist in a rotorcraft accidents – specialized in rotorcraft accidents in the flight safety group of a Rotorcraft OEM. He began his aviation career as an officer in the U.S. Air Force where he served as an instructor and evaluator helicopter pilot. Lee began working as part of what is now the Vertical Aviation Safety Team (VAST) in 2010. He has worked in the U.S. Helicopter and Safety Team since the inception in 2013 and has served as the government co-chair of the USHST Safety Analysis Safety Assurance Team since 2018. Thank you, Lee, for taking the time to be able to speak to us.

-Well, thank you for that introduction, Jeff. I really appreciate it. And thank you to the Committee for the invitation and opportunity to share this information on Air Ambulance Industry Accident Data and Analysis. Next slide, please.

As a roadmap for what I'd like to discuss today, I'm going to start out discussing the HAA Part 135 growth in the industry as measured through flight hours. From there, we'll look at some common accident metrics through counts and rates. Next, there will be observations from some of the HAA Part 135 accidents through USHST data, also from findings from the NTSB. And finally, I'll be discussing some of the USHST initiatives that are related to HAA 135. Next.

To begin with the growth of the HAA Part 135, I will frame this in two ways. To start out with, we'll frame it in the context of the overall US helicopter industry and then from there we'll drill down more specific to Part 135. So, we know that since 2016, as part of the FAA's requirement to provide a report to Congress, we have the actual flight hours for HAA Part 135 operations and when we put those alongside the annually administered general aviation Part 135 activity survey that the FAA conducts, we get a good idea of what share HAA Part 135 has within U.S. Helicopter ops. So, since 2016, when the report to Congress was first started, there's 16% of the hours on average going through 2023 that have been Part 135 ops. And that share has increased over that eight-year time period from 14% in 2016 to 19% in 2023. Also in that time period, HAA Part 135 has ranked in one of the top three industry segments for each one of the hours from. Next.

Now, if we drill that down into Part 135 specific flight hours, since 2016, HAA Part 135 is accounted for 52% of the U.S. helicopter 135 hours. That's about three times higher than any of the other U.S. helicopter Part 135 industry segments. The most prominent ones that would come to mind would be offshore oil and gas and also air tours. And the share of HAA Part 135 along the Part 135 helicopter segment has increased over the last eight years from 44% in 2016 to 67% in 2023. Next.

As an overarching statement, since the report to Congress began, there's been a 23% increase in HAA Part 135 flight hours from 2016 through 2023.

This next portion of the presentation will discuss the accident metrics from 2016 through most to 2024. I say most to 2024 because of the time this presentation was put together, I only had data available through October of this current year. So, it's not quite nine years' worth of data. This is really just an overview slide of what we'll be talking about because we need some context in order to compare this to the rest of the overall helicopter industry, but we'll be looking at both counts and rates, and we'll be looking at those according to accidents, fatal accidents, and fatalities. Next.

So, for HAA Part 135 accidents, you can see there were 58 overall accidents in that timeframe for rate at 1.42 per 100,000 flight hours. What that amounted to was HAA Part 135 accounted for 6% of the 962 U.S. helicopter accidents that occurred in this timeframe. That was and the rate of 1.42 was about three times lower than what the rest of US helicopter industry segments were combined. The best year for accidents for HAA Part 135 was in 2020 where we saw a count of three and a rate of 0.7. The worst year being 2022 with a count of 12 and a rate of 2.8 per 100,000 flight hours. Next please.

Shifting to fatal accidents. There was a count of 10 in that time period we're looking at for a rate of 0.24 for HAA Part 135 and you can see that on the right side of the slide, again, this was 6% of the overall US helicopter fatal accident total and the rate also was about three times lower than what the rate was for all the other industry segments that were combined. The best years for fatal accidents, there were four of them, 2018, 2020, 2021 and 2022, where there were not any fatal accidents that occurred. So obviously a rate of zero. The worst year was 2019 with a count of three and a rate of 0.7 per 100,000 flight hours. Next, please.

And the final metric that we'll look at on this is fatalities. 27 fatalities for HAA Part 135 for the time period we're looking at for rate of 0.66 per 100,000 flight hours. The 27 fatalities comprised 9% of the total U.S. helicopter fatalities for this time frame. And the rate was about two times lower than the rest of U.S. helicopter industry segments combined. Again, this will be the same, best years as the previous slide. No fatal accidents mean no

fatalities. So, a count and rate of zero for 2018, 2020, 2021 and 2022. The worst year with 2017 with seven fatalities at a rate of 1.63 per 100,000 flight hours. Next, please.

But now I'd like to talk about observations from some of the accidents and to start out with will give an overview of just the overall helicopter industry and then we'll drill down to HAA Part 135. So, the chart that you see in front of you is from the U.S. Helicopter Safety Team and it's the occurrence categories that were assigned across all helicopter accidents for the 10-year timeframe of 2009 through 2018. The methodology that the U.S. Helicopter Safety Team uses is based on the CAST/ICAO Common Taxonomy Teams, aviation occurrence categories, and it's a methodology that is also used by the Commercial Aviation Safety Team for transport airplanes and for the General Aviation Joint Safety Committee for small airplanes so it's common across all three of those government industry safety teams. I don't have every occurrence category for the helicopter fatal accident chart shown, just in the interest of compressing these down to the highest percentage ones. And what you see on the chart covers 86% of the 198 fatal accidents that occurred during that time. Next.

You can see on the far-left side of the chart, the combined, those three categories accounted for 64% of the fatal accidents for U.S. helicopters in this 10-year timeframe. You'll note on the far-left side of the chart, 27% where it says collision with obstacle or terrain is actually an aggregation of three separate occurrence categories, the most prominent of those is low altitude operations which accounted for the highest part of that 27%, but it also includes CFIT and includes collision during take-off or landing. All of those are a variety of striking an object or terrain during flight, so that's why they were aggregated together. Next.

Again, there are 13 more occurrence categories I'm not showing on this slide because each of those accounted for less than 4% of the total. So, all this was to provide context for the next slide. Next slide, please.

Which shows the HAA Part 135 numbers for this same 10-year timeframe. And you can see on the left side of the chart that those three high areas that were on the previous chart are here as well. But in this case, they account for even more of a percentage, 81% total versus 64% total in those three areas. The relative order is a little bit different because you can see unintended flight in IMC is the top bar, followed by collision with obstacle or terrain, and then lost that control during flight. Next.

So, if we look at the most recent six-year timeframe, 2019 through 2024, you'll note that those three categories that had the highest bars on the previous slide, we don't see that in this case. There there's only a single, fatal accident for each one of those and combined they accounted for 42% of the fatal events that occurred in that six-year time frame. One

caveat I will add to this chart is that on the far left you can see that we have two fatal accidents that are currently in the unknown and that is because the investigations are open and there's not been enough information released yet to credibly classify them. So, at some point in time they will be classified and it's possible that they may go into one of those three higher interest areas that we've mentioned. Next.

Coming from the USHST data, I wanted to explore the NTSB findings in an overview, also for HAA 135 fatal accidents, and this will be for the 2016 to 2024 timeframe. So really going back to that time period that I had early in the brief where we talked about when the report to Congress started. So, for those familiar with the NTSB finding codes, when an investigation is completed, the NTSB assigns finding codes to each accident and they can assign multiple finding codes as possible for a given accident to have each one of the finding categories represented that you see on this chart. And under each one of these categories there can also be multiple findings that are assigned under that category. So, for the time period that we're looking at, there were finding codes available for six of the fatal HAA Part 135 accidents that had occurred. So, the percentages you see are with a denominator of six being used. You can see there were five of the six that had both environmental and personnel issues that were noted, four of the six had aircraft issues, and two had organizational issues. Next.

In the second row, it shows you the total number of findings that were assigned. So, there were 44 total findings that were assigned, and you can see the leaders in that area were environmental with 19 and then followed by personnel with 11. Next.

If we drill down into each one of these specific finding kind of areas to a higher level of granularity, under the environment area, the five fatal accidents that noted an environmental issue, the specific areas that were noted in three of five were ceiling, visibility, and precipitation issues, in two of five were light conditions, and then the remaining four areas that are covered at the bottom of the gray area you can see were noted in at least one of the fatal accidents. So, the five fatal accidents that noted in environmental finding code for the five had multiple environmental findings that were cited. Next.

Moving on to personnel issues for the five of the six fatal accidents that have personal issues. The most frequently cited in three of the five were the personnel's use of equipment and information. Next highest frequency was personnel's information processing or decisions and also perception, orientation, and illusion. And then one of five of those fatal accidents has the other four factors that we see there. Of those five fatal accidents that have personal issues cited, four of the five had multiple findings cited. Next.

For organizational issues, two of the fatal accidents had oversight issues. And then one of the two fatal accidents had one of the four factors you see there. There was only one of the two fatal accidents that had multiple organizational findings that were noted. Next.

And wrapping up with the fatal accident findings. There were four out of six that were in the aircraft area and all four had something related to performance control parameters and one of the four had a turbine engine issue that was also noted. Next.

This is what it looked like for the 42 cases of non-fatal HAA Part 135 accidents for that same timeframe and you can see that again, in the high concentration areas for the fatal accidents that had findings, environmental, personnel, and aircraft led the way in both of those. Next.

And there were 115 total findings that were assigned. You can see that of those 115, 40% were in personnel, 30% in environmental and then aircraft was the next highest with 25%. Next.

Just in the interest of time, I only cited the highest percentage under each one of these finding areas for the non-fatal HAA Part 135 accidents. So, under environmental it was object, animal, or substance that was in 33%. Under personnel, it was a personnel's use of equipment or information. And under aircraft, it was again performance control in 29% of cases. Next.

So, for the last portion of this presentation, I wanted to note some of the U.S. Helicopter Safety Team completed initiatives from 2018 to 2022. This is important within the context of Part 135 air ambulance operations because HAA was contributory to not only the analysis but the development, the implementation, and the promotion of these. So, the 16 areas you see on the left side of the slide covered areas from training to policy, to outreach, to technology and equipment. Also, on the slide on the right side, you see a special project that was also associated with this effort. The 58 Seconds to Live project, which was not only a video, but a training module that was developed, and this was specific to unintended IMC prevention. Next, please.

And finally, the current initiatives, the safety enhancements that the U.S. Helicopter Safety Team announced in 2023 going forward. The air ambulance community has been contributory to the development of these. There's two of the five there are currently in progress. The first one being promote conservative go to go decision making and then the fourth one that you see on the slide there, improved fatigue awareness and risk mitigation of scheduling factors leading to fatigue. So, the other three that are on there are ones that the USHST has queued up to launch, but they are not currently active as of yet. Next.

So, I intended to give an overview on the growth of HAA Part 135 operations based on what we've seen for the flight hours, review some of the common safety metrics of counts and rates according to accidents, fatal accidents, and fatalities. And then go through accident observations from both the USHST and the NTSB. We wrapped up with just an overview of some of the initiatives that the USHST has undertaken that involve HAA Part 135 air ambulance. And, along with that, those same initiatives have benefit to the broader helicopter community as well. So, when you're HAA ops, for most those, it has the benefit of improving safety across the board for us in the U.S. And that concludes my presentation. Thank you.

-Thanks, Lee, for the presentation. We will answer questions when we go into a committee discussion. So, we'll wait for that. So, thanks very much.

So, next, I would like to welcome our next speaker, Ben Clayton. Ben serves as the CEO for Life Flight Network, leading a team of nearly 900 dedicated professionals in the Pacific Northwest and Intermountain West. Ben joined Life Flight Network in 2015 and has filled a variety of operational, safety, and executive leadership roles of increasing responsibility, becoming the CEO on July 1, 2022. A skilled leader, Ben brings with him extensive experience in aviation safety, leadership, and complex operations. Ben also serves as a DOT appointee for the AAQPS Committee. Welcome Ben and thank you.

-Thanks, Jeff. And, man, Lee is a tough act to follow. I don't know if everybody noticed, but he hit his time within three seconds. So, well done, Lee, and, if you're not familiar, Lee sends out a monthly wrap up of all those statistics and I always look at those closely. Really great information for all of us to have. So, if you're not on that distro list, I would advocate jumping on. So, we can go to the next slide here.

Alright, so I was asked to provide an overview of what do we do in the area ambulance industry from a safety management system perspective. What do we do to try to keep ourselves and our patients safe from an aviation perspective and so we'll kind of talk through safety management systems a little bit although others have touched on that earlier today some of the technology and training tools that we look at, and then I'll briefly discuss the FAA oversight, but we've had discussions about that earlier as well. So next slide please.

So, what is a safety management system? So, this is critical for understanding what we do and what the FAA mandates that we do and if you could advance to the [sic]. So, the first thing, there are four pillars of [inaudible] and these are defined per the FAA. But the first one is policy, and that policy really represents the organization's commitment to safety. If you don't have any policies in place, people can't follow them. And so, then you can have organizational drift, and people are doing things maybe not in a standardized way, so it is

important to have some policies. And then next, go ahead to the next slide, is risk assessments, a safety risk assessment.

This is going to focus on identifying and mitigating risks, and this is where we really look to the employees to try to help identify and define those risks because they're the ones that are out there operating. I previously was a pilot at Life Flight so I would be out there looking at those things, operating on the line, seeing the things, and helping identify the risk. But we really lean on our employees to do that and report that up so that we can help solve it. And there's some formalized procedures there that the FAA mandates through preflight risk assessments and then they will interact if you're at a larger program with the operational control specialist who is also looking at risk mitigation on every single transport. Next slide, please.

And then you go to safety assurance, and this involves monitoring and evaluating safety performance. There are tools that we can use like flight data monitoring, which I'll talk about later, but you know, really, we want to make sure that the way we think we're operating is what is actually happening and that's where that safety assurance piece comes in. And so, it's not designed in a system to be like big brother watching necessarily, but it is designed to make sure you are monitoring the performance of your systems to make sure that they are functioning the way that you think it is. Next please.

And then you have safety promotion and this is where it is really incumbent on leaders in any safety sensitive organization that you're out there and you're promoting safety and you're putting your money where your mouth is and a lot of these things are expensive to do and I'll talk through some of those things but it is important for leaders at all levels to really be promoting safety and not just have it be lip service. And I do think that across our industry, the leaders that I work with closely and collaborate with are all very safety, have a very high safety mindset and are out there promoting safety consistently. Next.

So, this is kind of a slide that just shows a number of the things that we try to do in order to ensure that we have the right technology, the right tools that we can be as safe as possible in our industry. Well, one of the things is night vision goggles and if you're not familiar they enable you to see terrain obstacles and landing zones in near or total darkness and they just amplify the available light. And this is kind of a mockup of what it would look like on a night on the left side of the screen. You can see, you can't really see anything and on the right side of course you can see the terrain. So, obviously that's a huge safety tool that that many of us, most of us, in the industry is just standard. We're using them on every night flight, particularly in rural areas but again it is expensive. Night vision goggles are in excess of $10,000 or $12,000 each and they have maintenance cycles but it's such a great safety tool that the vast majority of us are using those.

Terrain awareness is another thing, another technology that is really important and it comes in a number of different ways. But you can have actually, in that picture that you see there is like a 3D synthetic vision version of terrain awareness and if you get too close to something in the picture there's a woman that lives in there and she'll yell at you, and it'll actually turn – that's a joke. It will turn the terrain or the tower red or yellow, and it'll tell you that you're too close. And so that's again a technology that we've leveraged across the industry to try to keep the pilots to have really good self-awareness about where they are.

And then in the bottom right, you see flight data monitoring. And this is another tool that we can use to analyze how our pilots are flying. Are they meeting the parameters that we expect them to meet? And then frequently it helps them self-identify like, "Oh, I didn't realize I was flying a little bit higher rated descent on that approach." And we've actually had inexperienced pilots that will call and say, "Hey, I had a kind of a weird thing happen. Can you pull the flight data for us, and can we walk through it so I can see, you know, if my perception of what was happening was actually happening?" And so, you know, the flight data monitoring is just another piece of technology that we can leverage and that many in the industry are moving towards.

And so, you know, really technology is a big piece of this as well as training and as part of an SMS, we can feed those technology things and all this data back into the system and allow us to continue to train to that and to train in order to improve and get better. Next slide please.

Alright. Several have already mentioned this, so, I will talk briefly about this, but the majority of air ambulance providers are operating on a Part 135 certificate which we've talked which is highly regulated by the FAA. There's a number of rules and what will happen is if you're operating an air ambulance you have a Part 135, you're a smaller operator you'll have what's called a PLI, and then as you grow, that team that's dedicated from the FAA will grow. And so, some companies will have, you know, 10 or 15 or more dedicated FAA personnel that are just managing their certificate and the idea is to make sure that it's part of that safety assurance piece of an SMS where we're making sure that things are being operated the way that we think it's being operated. And it has become a really good dialogue and partnership back and forth between the FAA and the operators to make sure that we're out there and being as safe as we possibly can.

Some of the programs that we've discussed, the FAA's Part five SMS. It was voluntary for Part 135 operators. It's now becoming mandatory for helicopter air ambulances and so operators who have long time had an SMS are just now, you know, moving that forward to fully meet all of the specific requirements of the FAA's version of an SMS. Aviation Safety Action Program is another good program. Line Operations Safety Audits. So, both of those are kind of, they're targeted for the line personnel so that they can self-report things that

they think that they might have messed up and it helps them learn and get better. And then the LOSA program is again with assurance where we can put people in the aircraft and observe how the pilots are doing and then provide feedback from time to time and watch them, that's outside of the annual check rides they're doing. And then we talked about flight data monitoring and Flight Operational Quality Assurance that it feeds in. [inaudible] just manage the flight data monitoring program. Next please.

And then so I just kind of close here with a note about industry collaboration, and Lee did a really good job of highlighting the USHST. [inaudible] talked about the Air Medical Operators Association, AMOA. I do, by the various boards that I'm on in the industry, have a really good collaborative relationship, many of us, and to focus on safety. And we routinely meet in person to talk through how can we be better from a safety perspective, how can we share information to make sure that if I make a mistake or something weird happens to me, I can share that with others so that they can perhaps, you know, learn from that and we can all learn and grow and be better. So, with that, you can go to the next slide, but it's the question slide. And that is all that I have. Okay, didn't do it quite as good as Lee did. I'm 25 seconds.

-Alright, thanks Ben. That was really, really good. So, I appreciate the presentation. So right now, I'd like to welcome back all of the Committee members as we can open up a discussion about the last 2 topics. I think Eric, you've had your hand up for a bit, your virtual hand, and so maybe you want to kick off the discussion. Or maybe it was inadvertent. So let me just open it up for the group then.

-One of the things that I would just touch on in Lee's data, that's helicopter, and so as we know, just it for us to think about as a Committee, we do want to look at the whole picture which is fixed-wing as well and the last few years we have seen a number of those accidents so we should just keep that in mind as well as we try to come up with recommendations.

-Rob?

-I just would like to highlight from Ben's presentation that some of the programs that Ben mentioned, this Aviation Safety Action Program, the Flight Operations Quality Assurance Program, FOQA, etc. Those are what we consider voluntary programs in the FAA. So, Part 135 operators are not obligated to have those programs. But our data inside the FAA shows huge success when air carriers have those programs. So I just wanted to highlight that little nuance and that, if at some point during the Subcommittees' discussions, voluntary programs within the flight standard services is one of the things that fall under my responsibilities, so if there's an interest in having or hearing about the successes of those programs to help develop any recommendations, please let me know if there's an interest in hearing more. Over.

-Thank you. Grace.

-I'm wondering, so for the last discussion, that was really helpful, I'm wondering if, you know, each of the technology improvements – you know, you can sort of always be introducing technology improvements – is there sort of the equivalent of the graphs that we saw for the rotor accidents of when night vision goggles are introduced, then we see, you know, X lower rates of accidents during those kinds of flying conditions or those kinds of corollary statistics?

-So, Grace, was that question for me?

-It's for whomever would have an answer to it.

-Okay, I guess I can start out just by saying that one of the challenges in that – which I think is a great question – is the NTSB final investigative reports do not always denote whether night vision goggles were used or not. So, it becomes a little more problematic to say, you know, I have a clear line in the sand on, yes, we've seen X amount of improvement over, you know, certain amount of time, when we don't know, you know, how many of those night flights necessarily had goggles versus the ones that did not. I think just, you know, anecdotally, you know sort of as Ben addressed it, everyone, you know, understands that, you know, night vision goggles are a compliment safety add to safety, but quantifying that with the data we have available instead would be a little more of an uphill climb.

-Great. That's super helpful. And then I guess for the flight operator, and I'm sorry I have too many names on here and I am always the one who forgets the names, so who was just presenting. Do you have standards for like amortizing certain safety purchases like over payers or do you have standards for how that gets allocated across finance, like in your financing mechanisms? I'm thinking like with quality comes investment, with investment comes cost somewhere and trying to understand where that flows and whether there are standards to that.

-I don't know that I can speak for everybody. I'll say for us, we consider those capital assets, and we depreciate those over time, and then we replace them when we need it. But we have kind of from us, and I think many in the industry, is just a standard level of safety that we just do and there would be no, I'm not explaining that well, but I'll pause.

-Tom?

-Thanks. I think it's an interesting question because IHST, the previous of the USHST, actually did quite a lot of work on return on investment on safety initiatives. And, you know,

whether companies use those or not, I know some of the big OEMs are certainly using those, and probably some of the larger organizations, takes a fair bit to do that. It is important to also understand, and I think going back to Rob's comments of what is the FAA regulatory environment between voluntary. So, you know, back when I was the president of AMES at the worst times of crashes, you know, we lived through that and we have seen a really dramatic, you know, it's not perfect by any means, but a dramatic reduction since 2008, which was kind of the worst year. So, people have made a lot of progress. I think it would be worthwhile looking at 2009, the NTSB did the biggest study ever, the biggest four-day hearing on air ambulances issued. A lot of recommendations and some of those were interesting. So, they issued recommendations to HHS about how HHS was actually paying for safety and quality and what they were thinking about that. They made recommendations to FICEMS about patient selection. I think it would probably be valuable for the Committee to return to looking at those. The FAA made a lot of progress in the 2014-15 changeover, but did not require night vision goggles, nor required autopilots as a requirement in the aircraft even though much of the industry has voluntarily accepted those. So, I think those would be useful documents for this Committee to go back and review.

-Thanks, Tom. Jason?

-And just to add to Ben's point a little bit, I would say that, on average, the majority of the operators out there do consider the safety equipment, the investment in training, things like that to be capital expenditures. And there's also the complexity of the patient's involvement in a flight since we have had more and more people go to rural areas and we have you know determined that speed of access for the aircraft is important to patient outcomes. We've pushed bases out further away from central locations, which means it's not uncommon to have 3 flight legs to move a patient on one of those legs. Sometimes even more. So, these really end up becoming fixed costs that an operator has to accept and commit to investing in order to maintain the ability to serve a community and to do that safely versus something that necessarily gets passed on to the actual consumer, if you will. I think the other thing that's probably important to call out and I think it may lead towards one of the questions that's in the queue. Lee is absolutely right. It's difficult to tie safety enhancements directly to the data in part because of the way the data has been recorded over the years or is coded currently. And this, you know, could be an important discussion for us to have about taking a look at what things are actually called out in reporting as finding codes and is there, you know, a need to revise what is currently in the system.

-Great, thanks. Jason. Any other comments? Lee, I think he's going to comment about the infrastructure and codes there from what Jason just said.

-I would just, I guess, you know, double click on that point that, you know, recently I gave a presentation and NTSB was present. They were talking about the data that they record that we can retrieve from the docket and that sort of thing, and it very much is either they don't know if it's used until we tell them it's used or, if it's not present, they don't know unless we give them that feedback. So, you know, Jason's point is a great one. If there's a certain area that we have not been able to track what the progress has been on something, then that's got to be feedback given to them on the things that are documented on investigations that are made available to people like me who retrieve data from the docket.

-Okay, great. Thanks. I think since we're on the – I want to get back to this question that was posed before we broke for lunch and I think it said this is a good group of presenters to be able to bring this up, but it's in regard to patient safety. Is there a standard against helicopter shopping when one air service turns down a transport due to weather so hospital keeps trying other services to see if another will take it during bad weather. This group, I know that we all have, I have feelings about this, so I think it's probably all going to be the same, but I'm very interested in this part of the discussion. I see that Eileen, do you want to start off on this discussion?

-I can. We did a video on helicopter shopping years ago when this was pretty prevalent. There are standards within the CAMTS standards that also address it as well as for communications policies that address helicopter shopping. We do not see it as much now as we did maybe five or ten years ago.

-Jason.

-Yeah, and, I would absolutely agree with Eileen's comments, and we use a lot of material from the previous years to educate our requesters and people in the field, especially if anything comes up where we're concerned about somebody kind of heading down this road. I did want to call out that there's probably a fine line to what when we use the term helicopter shopping, we're referring to a single requester calling multiple vendors to try and get somebody to fly their patient and usually they're getting an answer of no relating to weather. You know, the tricky part here is that it's never a black and white world. We do have times where we have geographical barriers that kind of separate weather and so calling a requester that maybe is on the east side of a ridge line and in clouds and fog and can't fly because of weather versus calling a requester that maybe is a little bit further away but is on the west side of a ridge line and in clear skies, right, you know, these types of variances or complexities come up and so I think a lot of communication centers create essentially an algorithm or workflow for how they deal with multiple requests to a location, and that may escalate from VFR aircraft to aircraft capable of instrument flight. And then, within two or three calls it stops, but probably the most important thing is that pilots are informed about any other requests, any other turn downs, and that we have, you know, a

very specific safety protocol to kind of walk through assessing the risk here and making a decision. And this is included in preflight risk analysis that the pilots, and often the operational control center, have to perform.

-And then I would just kind of add is that, from my program, there's the weather turn down, and every single time that we turn down a flight or, since Ben and I are in the same area, there's always a line of communication that we can talk to each other about what's going on. It's really about communication. And that'll be my input to the discussion. But Ben, please go ahead.

-Yeah, thanks, I was going to echo everything that Eileen and Jason and Jeff said. I think that it has gone way down in recent years. And I think a big part of that is through industry collaboration. And, you know, when AMOA in particular, we meet there, and everybody is very much aligned with helicopter shopping is unacceptable and to Jeff's point, keeping the lines of communication open, so if we have something we can't turn it down, but I know that Jeff has a base that's in a different geographical location, our comms spec will pick up the phone and call them and tell them, but again communicate that something has been turned down. I think that the pressures that we face on that operator's side is sometimes these hospitals are desperate to get rid of their patient. They're worried the patient's going to die in their hospital and they want to get them out and so they may not understand the danger that they're putting people in if they're making all those multiple phone calls and just trying to get somebody. So, I think it's incumbent on us as an industry to be educating the hospitals and the EMS agencies that, hey, if it's not safe to do, then, you know, we can't do it. We'll try everything we can safely, but there there's a line that we cannot cross, and we can't, sometimes we can't get to your patient because the weather just makes it unsafe.

-Thanks Ben. Nolan?

-I think there's another part to this that we really haven't addressed also. There are some operators out there that have a business model of working in the VFR-only world where you have other operators at work in the VFR and IFR world. They have the infrastructure that it is safe for them to move a patient by using routings, by using special instrument procedures, and things of that nature, and I as an individual don't look at that as aircraft shopping, it is looking for a capability that that maybe one operator has when the, I'm not talking about through thunderstorms and things of that nature, but if it's just low weather and stuff like that, that an operator can use their special instrument procedures or their route structure to move a patient safely. That is a legitimate operation to move patients in a safe manner and there is a very large infrastructure of that within the NAS that not only the FAA, but the industry themselves has invested in, and I do see that that being a viable option to turn downs at times and we should not forget that part of it.

-Great. Thanks, Nolan. Rob?

-I just also little bit of I guess maybe a tangent but just want to maybe put it out there for the conversation with the Flight Safety Subcommittee too. And that's also the conversation around technology. I think Tom Judge, I'd maybe ask you your opinion on this as well. If you look at a map, a heat map of where the FAA has deployed weather cameras, for example, you find that those weather cameras in certain parts of the country do a very good job of mitigating risks of within-route weather, and the US Helicopter Safety Team does have some data where we can overlay metrics of where those weather cameras are located and compared to where heat spots are, for example, with just general helicopter accidents in general. There's definitely a correlation where there are more accidents in locations where the weather cameras aren't. So that's a capital infrastructure, you know, investment that's, you know, partnership with industry between the FAA. But I think it's definitely something that we should be talking about, and was not aware or excuse me, I'm not aware if everybody on the call was aware of the FAA's weather camera program and it's use in its success in mitigating risks. Over.

-Thanks, Rob. Tom?

-We have deployed a lot of those cameras in Maine and that makes a big difference. I think another piece of Committee if we're making recommendations to Congress, in Part 121 the airline world, we have airport improvement funds, right, and then those money gets spread out to airports and helps improve them. We don't really have anything in a low altitude infrastructure on a policy basis. And that's, you know, going back even to 2008, AMES made comments about low altitude infrastructure and the need for investment. We've seen some questions about teleports. There was, you know, at the FAA Info Share meeting, there was a presentation on accidents at heliports and hospital heliports. I think this remains a big issue and as we're looking at this, it should be certainly part of the mix of what is the public investment in infrastructure that's needed to support low altitude safe operations.

-Alright, thanks everyone. Thanks, Tom. Okay, so we're at the one-minute mark here. Is there any other discussion? Points for the Committee? If not, I'm going to move us onto our next speaker. So, I would like to welcome Eileen Frazer.

Eileen is the Executive Director of the Commission on Accreditation of Medical Transport Systems, which is CAMTS, since its inception in 1990 and has served as the Executive Director for CAMTS Global. Eileen is a former chief white nurse who served as the Safety Committee Chair for CAMTS and did the feasibility study in 1988 that led to the development of CAMTS. Eileen also serves as the appointed accrediting body representative for this Committee. Welcome, Eileen.

-Thank you. Welcome, everyone. Next slide, please.

So, the mission of CAMTS is we are a peer review organization, nonprofit, and we're dedicated to improving the quality of patient care and safety of the transport environment. This is our vision and our values. I won't read through those. Next slide, please.

The types of service that are eligible for our accreditation are rotor wing, fixed-wing, surface or ground, many times there are a combination of services that we accredit, medical escort on commercial airlines. We added in recent years special operations medical retrieval and also mobile integrated health, which is coming up more and more in our United States environment. Some people call it community paramedicine. Next slide, please.

So, why are we here? I just wanted to go back through a little bit of history and, forgive me, many of you are know exactly what I'm talking about or heard of before. So just bear with me. In the early 1980s, there were no published standards that were specific to the civilian sector of medical transport. ASHBEAMs had their first meeting in 1980 and started to write some guidelines. The Nurses Association votes in practice standards. The NTSB did a study in 1988. And then we incorporated a lot of these guidelines into our first set of standards when we formed in 1990. Next slide please.

The other reason we started was there were a lot of accidents and there was a question before about night vision goggles and in the 1980s, by 1988, weather was the highest probable cause for 23 accidents. By the NTSB definition, 21 of those 23 occurred at night and they were fatal, fatal accidents. Next slide, please.

So, with the guidelines that we got together in 1988 and 1989, we were invited to visit several hospital base programs and kind of beta test what these guidelines were telling us. Some of the issues that we found were patient care issues. For example, we would ask the crew, well, what do you do if you're, if you're doing CPR? Do you have to get out of your seat belt to do that? And what about takeoffs and landings? You should – are you telling the pilot you're out of seat belt? We also looked at patients that were being transported with oxygen, the portable oxygen cylinder between their legs and not secured in any way. So, these were things that we saw when we did our initial beta testing. Also, the medical director's involvement was minimal. In those days the medical director was usually assigned this as an extra assignment as an ER physician. Next slide.

So, we started with five members of CAMTS. Our philosophy is that we have members on the board from associations, from professional associations. I won't go through this whole list. Today we have 20, but they do represent every discipline that could possibly be involved in medical transport, including the operators, including communicators. We also have a US TransCOM liaison member on the board. And the board is responsible for the

standards, approving standards, and also for the accreditation decisions. Most meetings we have anywhere from 16 to 24 decisions to make and we meet four times a year. Next slide, please.

The factors that affect the creation of standards. They have to be specific enough to be measurable as we talked about earlier and meaningful, but also adaptable because there's variables like regulations, local, state, national, medical team differences, and available resources. And I was never more aware of this than I was since we moved to the San Juan Islands about seven years ago and Jeff and Ben can verify this. Patients that have to be moved off the island - we have one critical access hospital – if they need any kind of definitive care, they'd have to wait for a ferry, which maybe goes back and forth four times a day, or they can fly off. That's about the only two ways they're going to get there. And if they wait for the ferry, it's an hour and a half to Anacortes. It's then about an hour and a half to Bellingham or about two and a half hours, if you're lucky, to go to Seattle and get there without traffic. So that's kind of what you're dealing with. Next slide, please.

We also review the accidents and incidents in all of the programs that are accredited. There are over now 160 programs accredited in the US. They must report their accidents and incidents, and we look at those very carefully – see what we can learn. Next slide, please.

And I'll give you two examples. So, in my own example, I was chief flight nurse at a program in Allentown, Pennsylvania in 1981. We were in a BO 105. We were called to a scene of an accident at nighttime. They crashed, killed all four on board. The NTSB at the time said it was pilot error. When we talked to the EMS crew on scene, they told us that the patient was very inebriated and combative – big 18-year-old kid. We were in a BO105, so we surmised that they took off and shortly after crashed. We thought that probably what happened was the patient got out of his restraints – cloth restraints, we did not have at that time chemical restraints, and we did not even have a policy about a combative patient. And so, we felt that the patient interfered and one of the standards is there must be a barrier. Now in many aircraft today there's a normal barrier between the cockpit and the patient. But in these aircraft, this happens to be a Bell LongRanger, where the patient really could kick into the controls and to the pilot. Next slide, please.

Another example is the 2008 seven fatality accident that happened in Flagstaff, Arizona when two aircraft were approaching the hospital helipad. They collided about a fourth mile east of the helipad, killing all seven, four on one aircraft, three on another. We looked at this carefully to see what the communications policy should have been. They were not communicating with each other. They didn't share a common satellite tracking information. So, there were a lot of things that we had to look at. Strict enforcement of sterile cockpit – one crew member is always taking active part in watching. So many of these things we included into the standards as a result of that very tragic accident. Next slide, please.

And then also the NTSB, after that accident and number of others, they did the hearings in that Tom just referred to in February of 2009. And these are some of the recommendations that resulted from those hearings, and we have incorporated these into our standards. As of like 10 years ago, we require NVGs for the pilot and one crew member on rotor accident – on rotor operations. Next slide, please.

Standards are dynamic, they're not static, and that's why we review and revise them every two to three years. We're now our currently doing our 13th edition. We're still operating under the 12th. But if you look at the left side of the graph, those were kind of the technologies that weren't available when I was flying, compared to the right side of the graph. And I think certainly we can say we've lowered a lot of risk with these technologies. Next slide, please.

In 2012, we produced a book called Safety and Quality in Medical Transport Systems. Safety culture is a very big part of this book as well as I wanted to comment on one of the things we talked about before our lunch break. Fatigue risk management is very important, and we have experts that contributed chapters to this book. Fatigue risk management is very tricky for medical personnel because of the way different operations are. If we look – if we look at our old standards, we were saying no more than 12-hour shifts. And then we were getting comments like, yeah, but 'till I do my shift and drive home two hours and come back the next day, I'm really doing a - I get more rest on a 24-hour shift. So, we looked at that and we have certain criteria if you're doing 24 hours that you must have. If you're doing over 24 hours because there's certain rural areas where they might only do one flight every three days, so, those kinds of things we have also criteria for, but they have to then only do one flight a day if they're doing in excess of 24-hour shifts. Next slide, please.

We also do a culture safety tool that we develop from AHRQ that looks at the authority, professionalism, the organizational dynamics, and how we can look at – there's certain questions for each of those. All of the staff members, all the employees get this culture tool prior to us coming out and doing an audit. The scores and comments are submitted electronically by each employee and then we come up with – next slide, please.

And there's the summary of what the safety culture survey does. If we don't have at least a 50% return, we won't get any feedback to the program because it wouldn't really be relevant. Next slide, please.

But this is the summary of what they've received showing each of the things that the personnel are questioned about and how their safety culture survey compares to the CAMTS on average on the whole. And they will get a copy of this. Next slide, please.

Let's talk about patient care. I talked a lot about safety, but patient care, we look very closely at types of care. Every time we look at a service, whether it's their policies, their protocols, we refer back to what their mission is and what they're trying to – what types of patients they are trying to take care of. And we separate into basic, advanced, critical care, and specialty. Basic life support is mostly EMTs. Advanced life support is usually paramedic in an EMT. Critical care is usually nurse paramedic in the United States predominantly, but there's also staff crew, crews that are staff, like physician, nurse, two nurses, nurse respiratory care technicians. So, it depends on what their scope is. Specialty care is usually the pediatric neonatal population. It's important to know that in advanced life support, critical care and specialty care, we require at least two care providers on the aircraft or ambulance. Next slide, please.

So, we look at their quality management. Part of the quality management is – someone talked earlier about GAMUT. And we do require that they collect the GAMUT data, and they will show this to this in their summaries. We don't require them to report it because there's a cost to that, but they must collect the data. Utilization review – we have very specific criteria in the standards, but they also have their own, depending on the type of service they have. We look at education. Does it standardize? What are their competencies? How did they do those on an annual check? Skills and ARAM is required annually. Medical direction – we look at not only the medical directors – how he interferes or intercedes with the whole program as far as their staff meetings? Their quality meetings? Is he part of the safety committees? Does he look at the applicants and is he looking at what new people are coming in? Is he part of their training? That's very important. Next slide, please.

We also look and when we go out and do an audit, we will have the crew show us how they're using, where they're storing, where they're keeping their equipment, what equipment do they have, how did they use it, do they know how to use it. And so, the medical configuration is very important. Next slide, please.

We also have a list of safety education that's required and that’s on an annual basis, as well as survival training. And I won't go through all of those in interest of time. Next slide, please.

The medical direction I mentioned – what we do with medical protocols – we found from many years ago that many of the protocols we were receiving, and that's part of what they have to send in as an attachment, were really basically ALS protocols, but they were calling themselves critical care. So, when we look at those protocols, we have a physician-led committee that develops criteria for each of the protocols and they'll match that with what current medical practices there are and then they'll send recommendations back to the medical director about if they want to recommend me what they should use to update their protocols. Next slide, please.

This is just a shot of – I talked about medical configuration for pediatric, for neonatal transports – these are equipment that could possibly, should possibly, be added. Is there space for this equipment? Where does it go? How is it secured? And that kind of thing. So, if we are visiting a program that does neonatal transport, we will have a look at how they put the equipment on board and how it's used. Next slide, please.

Communications is a very big section of the standards that includes the comms specs training, staffing, and are they involved in safety QM and staff meetings? Next slide, please.

Pilot qualifications – this is the rotor wing section. And then there's also a fixed-wing section.

And here we can, because we're doing standards, not regulations, we can go over and above what the standards are. And so, we require 2,000 total flight hours for rotor wing pilots, or if they have 1,500 at least but with recent experience that exceeds the pre-hire qualifications of the operator. And we often get questions like, well, I couldn't hire a pilot because you have 2,000 hours there. He had 1,800 hours and he had all kinds of EMS experience and that's silly. So, what we do now is next slide, please.

This is, I won't go through this, this is the fixed-wing pilot qualifications and we're kind of skipping over the fixed-wing part of this. I hope we get into more conversations about fixed-wing, later because, as one of you pointed out, there have been some fixed-wing accidents as well. Next slide.

So, can you go back two slides? I wanted to make a point about the pilot's qualifications. Thank you. I started to say that when we started to see there were pilot shortages, we developed a way for the operator to send in their risk tool. If they have a risk tool that lists what experiences they feel are very important for a pilot pre-hire, even if they don't quite meet the 2,000-flight hour total, they can send in this risk tool and the Aviation Advisory Committee will look at it and make recommendations on how they can use this and improve it. And we also will look at that then in their total quality, in a quality management program, to make sure that they are looking at that backwards and seeing, collecting data on the pilots they do hire with less hours but maybe the experience they need. Next slide.

-Eileen, we've got about one more minute.

-Alright, I'll go to the end. Last slide. Oh, can I get the slide before that? This is what our unexpected challenge was a few years ago with COVID and I just wanted to bring this up because we had to rewrite policies, we couldn't go out and visit programs. We wanted to make sure we were keeping everyone up with all the standards so we did a lot of Zoom looks and we did something called conditional accreditation when we couldn't go out and

visit because that's very important. So that's over, behind us. Hopefully, we don't have to do this again.

And last slide, I'm just going to thank you for the presentation. Thank you.

-Thanks, Eileen. And thanks for all the work that you've done as the founder of CAMTS. I cannot tell you, as what all of us that are on the line here, you've done an incredible job of helping us meet the standards to practice safely.

-It wasn't me alone but thank you. Thank you, Jeff.

-So now, I'd like to be able to move on to Eric Chaney and Dr. Clay Mann. Eric Chaney is a result driven emergency medical services program manager with over 35 years of experience developing and interpreting regulatory requirements, laws, doctrine, policy, and program guidance for local, state, and federal fire and emergency services agencies. In his current role as an EMS specialist with the Department of Transportation, he serves as the project manager for the National EMS Information System, NEMSIS, and he is also joined by Dr. Clay Mann. Dr. Mann, who currently serves as the principal investigator for the National EMS Information System, Tactical Assistance Center. He has published 190 peer reviewed articles dealing with traumatic injuries to children, trauma, children trauma system evaluations, cardiac and trauma resuscitation, pediatric emergency department readiness, and the role of emergency medical services in healthcare. Please welcome Eric and Dr. Mann.

-Thank you, sir. Go to the next slide, please.

So, I want to just give you a very high-level overview of NEMSIS today and begin there and take you into some data from 2023 and 2024 that we pulled specifically for this presentation. So first of all, to be clear, NEMSIS is not software. NEMSIS is basically a system to standardize EMS documentation and data collection across the country, ideally to share that data for projects such as this on a national level and then be able to break it down all the way through to the granular level at the actual response. Next slide, please.

So, if you think about it as NEMSIS as a palette of data elements, that's the blue disk at the bottom of the visual you see here, it's approximately 600 standard elements. Each ambulance service or in this case, aeromedical service, has the ability to select within those data elements specific elements to their operational needs. A subset of that data is sent to the state offices who require, in this case, aeromedical services to report their activities to them, whether that be because they license the services themselves or whether that be because they license the clinicians, the paramedics, working on the ambulance and as part of that there is a requirement for data reporting. A subset of that

data then goes to the national data set, which is what we're going to be pulling from today. I show you this because there is a requirement that the national data set be included at each of the levels that you see here. So, the more granular you go in terms of locality, the more data that you have available. For today, we're going to be talking about the national data set. Next slide, please.

All 50 states, three territories, and the District of Columbia are reporting within the NEMSIS data system. So, this is as close to a census as you're going to get in the prehospital and really healthcare environment. Next slide, please.

This is a flow of data primarily for ground services, but if you think of it in terms of a car crash and reporting to 911, insert your ambulance or helicopter service where you see an ambulance on scene, and you're looking at the data that's collected within NEMSIS. We have dispatch data, we have response data in terms of aeromedical services, we have liftoff times, we'd have location for the incident, we would have when the unit departed, when the helicopter or fixed-wing departed, where it was transporting the patient to the type of patient care provided. All of that data is included within that palette of 600 data elements from NEMSIS. Then the other graphics that you see here is where this data is shared, and this is an example of just one of the committees that we share data with at the federal level. Next slide, please.

So, the timeliness of NEMSIS data is always discussed. This graphic just basically shows we know we can complete a patient care report. When a patient care report is completed at the scene, a paramedic hits final or send, that data can be in the national data repository within seven minutes of the event. We have approximately 85% of all the EMS activations in the country that we're going to get within 48 hours and that's what's in the little box represented there on the right-hand side. Next slide, please.

So, to get specific about aeromedical services within NEMSIS, e-disposition 07, primary role of the unit, in this case, aeromedical, you have two options: you can say you're an air transport helicopter or air transport fixed-wing. For calendar year 2023, we had 272,790 responses for helicopters that were documented within NEMSIS and then 48,991 for fixed-wing. Now I want to give you a caveat, a limitation of this data: if the state doesn't require the aeromedical services to report to the state EMS office as a part of that system, we would not have that data. A good example would be a helicopter service owned by a hospital system that uses simply nurses or critical care nurses to transport patients that do not use EMS. They may not be counted within the NEMSIS data set. Next slide, please.

So, once you select aeromedical or once you select fixed-wing – I'm sorry, fixed-wing or helicopter – you have the ability to indicate the type of services requested by the requesting authority. In this case, you have selections of emergency response which could be a

helicopter going to the scene of a motor vehicle crash. And intercept could be a similar event but for us that typically means the ambulance picked up the patient started towards a facility and met a helicopter in route because it was advantageous timewise to meet in a local, you know, someplace midpoint as opposed to waiting for a helicopter to come in or for the ambulance to do the complete transport. There's a hospital-hospital transfer, which is pretty straightforward. There's this other routine medical transport that's usually interfacility, and then emergency response mutual aid. We track emergency response mutual aid because a lot of times the state wants to know, or locality wants to know, if the ambulance – I'm sorry – in this case, if the helicopter or the fixed-wing came from an area outside their jurisdiction. So, really you could lump emergency response mutual aid with the top number, emergency response (primary response area), to get the overall emergency response number. Public assistance is just that. It could be any one of a number of things. It could be servicing law enforcement, helping them with search and rescue. And then standby could be any one of a number of things, from standing by at a large rock concert, standing by at a NASCAR event. These types of things are included within those numbers. You can see interfacility for helicopter is the primary reason for helicopter use and then, close behind, it's the emergency response to the scene whether it's mutual aid or whether it's within the primary response area. Fixed-wing tends to be hospital-to-hospital transfer. Obviously, they're not landing at the hospital. EMS clinicians code it this way because they're transporting the patient from the hospital usually by ambulance to the fixed-wing location where they're going to take off. Next slide, please.

What you have here is the incident location type. So, this is again a further breakdown. So, we looked at the primary role of the unit, the helicopter or the fixed-wing unit, and what you have in the first column under incident location where you see primary residence are the ICD-10 codes. And you have primary residence as sort of the overarching code but below that we do have the capability to look at, and it may not be relevant for this Committee, primary residence as a condo, an apartment complex, single family home, you know, you can break these things down into much more granular detail. It just depends on how far you want to go. Again, air transport for a helicopter, hospital is the number one location. Transport vehicle is indicated there as well as probably their second largest. And then fixed-wing, again, we're back to servicing hospitals. Next slide, please.

So, we took a look at this by state. We don't have all 50 states on here just because they didn't fit into the slide very clean so you could read it. But what you have are the primary role of the unit, whether it's air or fixed, or whether it's a helicopter or fixed-wing, and then the number of transports by state. Again, this is limited if the state doesn't require the data to be collected. So, you can see which states are the larger users of both services and then, the totals. This is again, 2023. Next slide, please.

So, we looked at 2024 to date, and today for us was the first of the month. So, we have air agency count. So, what you're seeing here is by state and again, they're not all out here just to make it fit on the slide. The number of air ambulances that are counted in the state, and, for us, that's based on a demographic file that's created within NEMSIS. For example, I see one for Maryland, probably the Maryland State Police System. However, there are other helicopters that function within the state of Maryland. So, this is an area where we base this on our demographic file, and you would have to know your state specifically to understand the relevance of the number that's there for air agency count. And then the event count, just broken down by state. Again, this is for 2024. And go to the next slide, please.

Before we get to questions, I just want to say, so for each of the counts that we have there, we have the ability to look at whether this hospital-to-hospital was an interfacility on an emergent basis, not an emergent basis, whether it was for trauma, cardiac, stroke, were they going to a trauma center from a local community hospital. A great deal of capability exists within NEMSIS and then Eileen mentioned what type of care was on the helicopter. We can look at the scope, whether there was a paramedic, whether there was an EMT on that helicopter – which you're not going to see an EMT – but primarily what you're going to be able to tell is what level of care was required based on the patient care report. So, my ask to this Committee is, as we move forward, please tell me what you would like to see from us. How much detail you would like to see? Is your interest in the operational data, the lift-off times, the transport times, the location times? And then we will work with Joe House, who you heard from earlier from the National Association of State EMS Officials, so that we can provide that data to you on the level that you're required. Questions, comments, or concerns?

-Eric, thank you very much. I think this is a good segue into our discussion from the Committee. So, I'd love to be able to welcome everyone back. As we come back, let's just start off with Eric and any questions from the group for the presentation, and then also for Eileen's presentation. Colonel Coffee?

-So, great presentations by both. My question was really, you piqued my interest really a lot with that TransCOM [inaudible] that's participating with you, Eileen. So, I wanted to know what kind of lesson learned, crosstalk, or things that you're kind of using to benchmark from the Department of Defense, because we have the same kinds of challenges sometimes when it comes to air ambulances in transport. So, what lessons learned, or benchmarking have you kind of gleaned from DOD in these efforts?

-Is that for me, Colonel?

-Yes, ma'am, it is.

-Okay, yeah, US TransCOM. Well, they approve, as you know, all civilian aircraft that are transporting patients, and so, we work with them to make sure that they know who's accredited. And what we commonly see is a question about who's really the operator? And this is a question that most people have. Well, are you accrediting an operator or a service? And we accredit a service and that's primarily the medical component. The operator's certainly a big part of that, but the operator could do all sorts of other things. Maybe they do charter or whatever and that's why we don't really accredit a per se operator, although it's confusing because there's some services that are named for the operator, but that's all they do. That's all the operator does. So that's where we kind of work together to decipher is this the service that you're looking at [inaudible] TransCOM and is it accredited? I don't know if that answers your question.

-No, no, it helps. The other thing, and you mentioned the accreditation piece, and I was kind of zeroing in on, you know, you brought up one of the challenges that you had by having to utilize Zoom during the COVID era for accrediting. But I look at it from a different lens and say, was that also an opportunity to expand the reach for reaching more people for accrediting.

-To expand? I'm sorry.

-Well, so, and maybe I didn't quite get it all, but cause I know you were running short on time at that piece, but you know, when I saw that you had to go through Zoom and do a virtual sort of accreditation piece, that that's certainly a challenge when you like to do those in person visits and really get a sense of what's going on. But I look at it from the other side saying that, well, that also gives you an opportunity to then expand your reach because you can obviously reach more people through Zoom in those types of platforms to get to the accreditation piece. So, I want to know if you're also using that. Go ahead.

-Oh yeah, during that time period, if it was a brand-new program, we just delayed a site visit because it is essential that we go out and do the audit in person. For re-accreds, what we did was delay it if we had to, or not even go, and sometimes that was a year away. So, we would do a Zoom sort of call just to see if they were in substantial compliance from what we could see and that would only be a year. There was no real way to expand during that time because, as I said, the primary, the people that are just applying, we really couldn't do anything with them until we could get out and do an audit, so those were delayed.

-Okay. No, copy all, and certainly appreciate the insight there. And again, I'm maybe looking at it just from that – maybe the logistics don't allow you to utilize, you know, the Zoom and those kinds of things to just broaden that aperture more. I certainly understand some of the challenges that you had there. So, I appreciate the response.

-Thanks for that discussion. Tom? You're on mute still.

-Eileen, thanks for that presentation and thank you for all your work over the years. Everyone should be giving you a huge round of applause here.

-No, no, no, no.

-You said there were about 150 programs accredited. Do you have what density, the percentage of that, is compared to the programs in the US?

-We figure – that's a hard thing to measure, Tom, because as you know, a program could have five different other named programs within it. So, it's hard to say, but we think we're at like maybe 75-80%.

-That's helpful. And I think relevant to this discussion is that states can't require, but accreditation is voluntary, states can't require it. Purchasers can require it, and in some cases, parts of the Federal Government do require accreditation and that may be something that this Committee really wants to think about. We know that in the oil and gas world the purchasers completely transformed, you know, the safety of operations in offshore oil platforms by just saying, if you're going to produce this for us, here's – we're going to give you a list of specifications, so it may be something this Committee really wants to think about. That interplay and I think, as Rob said, the interplay of regulatory and voluntary adoptions of standards.

-Eileen, I had a question, and I think it might not be out there anymore, but is there another accrediting body for air ambulance services or does it no longer exist anymore? Cause I'm just probably dating myself on when it was around. So, I just wanted to know.

-There is another service in the US called NAAMTA and I, it's too long of a name to spell it out for you, but that started back about 15 years ago. They are still in operation as far as I understand, but they have very few. They have accredited very few programs. There's also a European – EURAMI, it's called – who stole our standards and started their own European type of service. And they're mostly doing a lot of the fixed-wing by insurances, they're very connected to insurances. They also do rotorwing too. And there are some programs in the US that are accredited by both EURAMI and CAMTS.

-Thank you. All right. How about I'd like to go to – there was a very specific question for Eric and Dr. Mann on the – and I don't know if Eric you can see the question in the Q&A. I can read it out for everyone to hear. So, it says: I found there to be significant lack in NEMSIS data set compared to needed information for critical care transport, in particular vehicle

change for a single patient interaction with whitelisted procedures slash medications in the data set preventing the ability to submit more specific procedures, figure thoracostomy versus needle decompression – both get coded as tension pneumothorax relief in the national data set. The question is, is there consideration for more expanded reporting for CCT.

-So, I'll address the first part, and then, Dr. Mann, if you want to address any, please let me know. There is the fact that this NEMSIS data set was founded and developed based on the need for 911 ground ambulance service response. Over the years, it was adopted, and parts were added for critical care, that critical care on aeromedical services and on ground services. So, it has really expanded based on protocols, based on state protocols, and state desires. So, there are areas where it can be expanded upon and could be expanded upon if the right leadership made the request. Clay, did I miss anything?

-And the only thing I would add is, we do document procedures using ICD-10 PCS codes, or SNOMED CT codes. And so, the question is a good one. If there are specific codes that I get down to the granular question that might be related to the way that a procedure is done or completed, if it's captured by a SNOMED CT code or ICD-10 PCS code, we would capture it. If it's aggregated at some level, we don't do that at the national level. We collect all codes, but maybe at the state level, they may be collapsing, you know, child codes into parent codes, but at the national level, and at the state level, we suggest that not be done.

-Okay, thank you. Dr. Hinkley?

-Thank you, all. I wanted to ask Ms. Frazer. So, I think most of us on the Committee are aware that CAMTS standards are moving toward tiered levels of accreditation, and I just wondered what your thoughts were on how that could correlate with the charge of this Committee, to create tier levels of critical care transport programs.

-Thanks for that question, Bill. We completely gave up on that. Because it is so hard to define what critical care is. And every time we tried to ask the associations, like Critical Care Nurses, they really couldn't come up with it either because, you know, balloon pumps, for example, used to be “Oh that's really up there, that's critical care,” and now a lot of ground paramedic units are doing balloon pump transports. So how do you define it and tier it? And, you know, years ago, we learned from a bad experience where we would do accreditation with commendation. And then we would, we had very few that were given that accreditation and then we'd hear from other programs saying, “Oh, what do you mean? They shouldn't get commentated?” So, you know, it took – to develop the criteria to say how, who, and how belongs in this tier, it's too difficult. We'd appreciate any help out there

if you could because we know there's different levels of critical care, but to define them and actually put it into a standard, we just gave up on for the time being.

-I did not know that. Thank you.

-Okay, I think of note just in the Q&A, Krista has posted a Rotorcraft Occupation Protection Working Group Test 6 reports contain some numerous ideas and interventions that might be helpful. I think that would be great for the Committees to be able to use that as a resource as we're going through our Subcommittee process. Alright, we have about eight minutes. Questions? So, alright. Bill, do you have another question or, okay, Tom?

-It's on mute here. Question for Eric and Clay. So, 272,000 rotorcraft transports. The FAA's data was 385,000 in 2023. So, and as you explain, I can certainly understand some of that gap. That's a pretty big gap. And I'm wondering what you're doing and what you're potentially doing with NASEMSO to see if there's a way to close that gap to get that accurate – I mean. And some of the codes just looking at it very quickly in the slides seem to be like really? Is that really where a pickup is occurring? So, I think there's some of that thing and we I know we struggle with it in Maine with our state EMS office to try and line up those codes, but just kind of wondering how we're going get to the – I mean, it is big number still – but, how are we going get to, you know, sort of all of them?

-Yeah, it's an excellent question, an excellent point. What it really comes down to is working with the individual state EMS offices. I think what Clay mentioned earlier, and then Eileen referred to, we're writing these national data standards as kind of a, whether it's defined under community paramedicine, or critical care, or advanced life support or basic life support, and then, in this case, the type of response, the question really becomes at that state level what's required and how it's captured. And the desire at the state level is what's really going feed that national data set. So, we work closely with NASEMSO. We work with them very well. The question is on this particular topic, how do we help them evaluate at a state level what data is being reported into that state and what needs to be reported? What's the gap? And I think that's what you're asking, and I suspect – I don't know this for a fact – I suspect a lot of this comes from the inner facility transports where there are not EMS responses or emergency 911 responses, or these are healthcare system owned aeromedical assets that are not counted as part of the emergency medical services systems, so that data does not go to the state EMS office. I don't know that that's all the gap I suggest is significant. And then when you look at services, if you were to look at the data we provided for Alaska between 2023 and 2024, you're going see a significant increase, not because of increased services in Alaska, but because they have a young very aggressive data manager who's been doing a good job going out to services saying, wait a minute, you

have a requirement to report and you haven't been reporting. He has spent a significant time doing clean up and you can see that. The other one is California which shows a significant increase. Two very large metropolitan areas who historically had not reported to NEMSIS have been added this year, one of them being LA. So, you can imagine the impact on the California numbers just by adding Los Angeles to it.

-Great, that's incredible discussion there and really good about the numbers. Going back to Q&A. This is for you, Eileen. So, what is the initial cost for accreditation? What is the ongoing cost for accreditation? What is the anticipated clerical and labor hours involved in the process and is there any reimbursement benefits for services that are accrediting to help offset the cost? And I am smiling because I could probably answer that question.

-You can answer that.

-Yeah, how about – but I'll go to the expert, Eileen, how's that?

-Okay, so the cost is initially when you apply it's a thousand dollars and for that you get all the materials that are – most of them are online now – that you can submit. We asked for probably 120 some attachments that we look at before we even go out and look at a program. And so that's the initial application. Then it's $6,500. Once they submit all that information it is $6,500 plus there's an asset fee for each aircraft or ambulance that is in operation, not on call or not just waiting, those that are in operation. It gets expensive depending on how many aircraft and ambulances you have. So, you know, it depends on how far you're spread out as well because when we send site surveyors out, and the cost of the travel and their expenses are also reflected in your bill at the end of the survey. You, you were talking about – I forget there was one other question to that, Jeff?

-It was reimbursement, reimbursement – does it benefit your reimbursement?

-I wish I could say there was a sort of caveat that a program was accredited that they get higher reimbursement, but there isn't. But what we have found is that sometimes you can save on your aviation insurance and also you can save on med malpractice. And I encourage a lot of the programs to look at their insurers and say, “Look, these people have to have a lot higher qualifications. We should get a break on med mal.” And so those are the kind of things. It's, you know – what we hear from programs that go through the process, what they learned from going through the process is that it brought the whole – if they do it properly as a team – it brought the whole team together because they're all working towards a common goal and that's really one of the advantages of doing that. As far as time for the office. It's a lot of time. There's three right now, three executive staff members. And

we will look at each and every one of those 124 attachments. When we get them so that we can go back to the program and say you missed this completely. This is not what we were asking for. Or we can make comments in our online so that the sites surveyor knows to look more deeply into this specific attachment or area. It takes me or Dudley or Jan anywhere from 24 to 48 hours, uninterrupted, to go through all the attachments and write all our comments. So, there's a lot of work done ahead of time. That's because we don't want to come out and waste all your time asking all kinds of questions that we should know about already. So that's why we spend maybe two days on site for a single program.

-Alright, thanks, Eileen. Rob, we have less than a minute. Do you want to make a comment?

-I had a question, but it's not going to get done. So, I'll lower my hand.

-All right, well, we'll make sure that we answer it at the next discussion point, okay? Okay, all right. I'm going to hand this over to David then, and thanks for the great discussion.

-Yes, absolutely. Thank you all for your continued participation. We're going to take a 10-minute break.

BREAK – 10 Minutes

Okay, everyone, thank you for your diligence and for coming back on time. We will now get started with the final portion of our day and turn back over to our Committee Chair, Jeff Richey.

-Alright, thank you David. Alright, so, we're going to continue on here and so, the Department of Health and Human Services will accept oral comments, which must be limited to the objection, objections, the objectives of the Committee and limit to three minutes per person individual members of the public wish to present oral comments must register and provide a written copy of prepared remarks for inclusion in the meeting record and for circulation to the AAQPS Committee members for future meetings. All prepared remarks submitted on time will be considered as part of the meeting record for our first AAQPS committee meeting. We [did] not receive public comments. I guess if we received anything throughout the day, is there any questions that we haven't answered and I'm going to go back to my MITRE colleagues here to, to help me guide me through that.

Have you received anything? Or can I move on? Or maybe I've already answered all of them through piece. My guess is to keep things rolling. David, Michelle, anything from that standpoint?

-Yeah, Jeff, I was just going to say, as we've indicated before, we will be addressing any comments that weren't addressed during this call. And I don't think that we had anyone sign up. I think we can just move on.

-Okay, that sounds good. Thank you very much. I appreciate that. We're now going to proceed with the next piece of our agenda. Nolan Crawford. Nolan will provide the overview of the Federal Aviation and Air Ambulance Regulations and we will we introduced him earlier so I'm just going to pass the mic over to Nolan. Thanks Nolan.

-Hey, thank you again for allowing the FAA to be part of this, today and allowing us to have an opportunity to present the approved tasking for the Committee or the aviation Flight Safety Aviation Subcommittee in this forum today.

As previously described, we have a robust set of regulation orders and advisory circulars within the FAA. That we use to keep crews safe and patients safe. But what we would like to do is take the opportunity through this brief and talk about the tasking Congress sent down to us. And share that with the public and with the Subcommittee. Next slide, please.

Well, as an introduction to why we're here and why the Flight Safety Aviation Subcommittee was created to start with the Department of Transportation and coordination with the Department of Human and Health Services proposed the AAQPS to make recommendations in response to the No Surprise Act. Next slide, please.

For those that weren't here this morning, we went over some regulations. We went over how we manage our operators under the 135 program we went over some of the advisory circulars.

So Congress directed Department of Transportation and [Department of] Human [and] Health Services to establish the AAQPS to provide recommendations To the Secretary of Human [and] Health Services and the Secretary of Transportation on options to establish quality, patient safety, and clinical capability standards. For each clinical capability level on air ambulance, so what we did at the FAA is we tried to take the two things that was directed by Congress and we tried to take the two things that was directed by Congress and make a tasking out of that for the Flight Safety Aviation Subcommittees and further on for the Committee.

The Committee in consultation with some experts and other stakeholders shall develop a report. Of any of those recommendations and present those back to Congress. That's why we're here today. Next slide, please.

So, the FAA approved a notice of tasking for the advisory Subcommittee and it will be placed on the AAQPS website after this meeting – the ask is for the Committee to identify any potential regulatory guidance, operational gaps that are applicable to air ambulance operation. The Flight Safety Aviation Subcommittee should analyze things such as poor, integrated weather operations. Special technologies, specific technologies, excuse me, that would improve safety and flight capabilities.

That review doesn't have to be limited to the following, but some of these are just examples. Look at our rule set that we have under sub Part 135 sub Part L for helicopter air ambulance equipment operations and training requirements. Look at the advisory circulars we have out for helicopter air ambulance, emergency medical services for airplanes, any NTSB data that Lee talked about earlier today, any of those safety enhancements created by the U.S. helicopter safety team are any initiatives that the U.S. helicopter safety team may be working on today. Next slide, please.

The Flight Safety Aviation Subcommittee should also analyze some areas for air ambulance operations that exist or may need to be and need to be improved. But they should also think outside the box and look for any elements out there or anything that could improve flight safety as well as patient care and patient safety. Some of those examples could be weather reporting, could be landing zones from a ground and from a crew perspective, does it need reoccurring evaluations?

Maintenance reliability of the aircraft and the med gear onboard the aircraft. Helicopter availability. Look at why helicopters aren't available sometimes. Is it maintenance? Is it crew, is it? You know you name it and tell us what you find. The flight following aspect for potential safety increases. How are our weather minimums, whether that be VFR weather minimums or IFR weather minimums. Night operations into heliports. Do what we have out there today. Is it what we need? Do we need additional things? Next slide, please.

The Subcommittee should also look at the differences in air ambulance vehicle type services and technologies, whether that be fixed-wing, whether that be helicopters, whether that be powered lift to the future. Do we have the IFR VFR capabilities that we have today? Do they need to be improved? Do these vehicles have any type of limitations that exist, or should be considered, as we look at closing some of those gaps as they relate to LZs, whether that be off airport, off heliport, you know whether it be a scene pickup. Should we look at our standards for heliports? Is there anything that we should look at for general locations such as mountainous, remote, rural, metropolitan, seasonal impacts.

The door is kind of wide open from here. Like I said, I believe we have a robust set of rules, Orders, and advisory circulars. But, you know, we also realize there's room for improvement. There's going to be new technologies out there for flight and patient safety

and they should be considered. So, we ask when you do this report that you give us that type of information what you find. Next slide, please

The ask is to make it clear to us when you write this report should we make these gap changes through policy, rulemaking, guidance material, or any specialized training or other mechanisms identified by the Subcommittee. That we should at the FAA look at implementing and tell us how, you know, as what you find and what you think can improve not only the flight safety side of this, but in collaboration with the clinical side, what we can do to help patient care as well as patient safety. Next slide, please.

Alright, I know I went over a lot of stuff there relatively quickly trying to keep us on time here. But the flight safety Subcommittee through interdependency and critical thinking should work with the clinical standard Subcommittee to enhance flight safety, patient safety, and service reliability. That was the ask from Congress, that is the ask from us here at the FAA. The Subcommittee should describe any mechanisms, again, whether that be policy, whether it be rulemaking, whether it be guidance materials, operator-specific training that we can use to enhance safety.

The Flight Safety Aviation Subcommittee should analyze and maintain the air ambulance operational safety and enhanced patient care by utilizing all these experts here to give us the information we need to write the documents correctly, as to provide for a safe environment for crews and patients. That's all I have today. I appreciate you.

Jeff Richey
-Thanks, Nolan. So, I think right now I'd like to offer the back up to the Committee members to be able to offering discussions of what Nolan just went over. I do think it was really, really good. I think it really just sets what the tasks are for that Subcommittee. I'll open it up to the rest of the group right now. Tom.

-Thanks, Nolan. I think there's a there's a number of things. One of the things that I think we ought to also consider our guiding principles is the future as you mentioned. We are in just generational change both in aviation technology and in clinical, you know, technology and clinical safety. If you make recommendations that are just for today, I don't think the Committee will really have done the work that it could do.

As an example, we know that the airspace, especially in urban areas, is going to become much more complex for the FAA to manage. My guess is that you know from the US HST side working and now we've moved infrastructure work group to VAI. My guess is that that's going to require basically everybody to be on routes. Do we have the aircraft today for everyone to be able to fly reasonably precision whether it's BFR or IFR routes in order to for the FAA to manage the airspace safely with lots of new entrants. I think that's a piece. I

think another piece that we do have, we put a number of things into, you know, congressional policy. One is that back in 2012, you know Congress instructed the FAA to support what was then HEMS IFR. I think that there's probably more that can be done. We've certainly done a lot of that in Maine and we're certainly working with colleagues, the Life Flight Network and Intermountain Healthcare, you know, that we've met out at info share on some of these things about how to better support the IFR system. You know we worked with Rob, and we can detail that out in 2018 we wrote into the FAA reauthorizations the ability to improve rural runways using AIP money and I don't think that's been taken up the way it could be, nationally, and to do much more around weather. And I think those others are public investments or combination public and private investments that really ought to ought to be needed. And I don't know how, you know and Jason you're going to try with the Subcommittee that maybe we can get some ideas on paper as we look at this to move these ideas forward.

-Thanks, Tom. Any other discussions? Rob, do you want to bring up the question that you had like 20 minutes ago?

-Sure, I'm happy to. My question was to Eileen and some of her slides specifically around some of the voluntary, experience levels, you know, that the organization recommends. My question was focused on the availability of pilots in this industry, etc. I know there is, you know, with the increase in voluntary minimums that coupled with many of the rotary wing to fix wing transition, programs, the pilot shortage in the Part 121 community. Quite honestly, the precedence setting salaries we are seeing in the regional airlines, how is your organization looking at those challenges and trying to recruit or advise member organizations to recruit the best and brightest to this industry. How does the industry, you know, are you having discussions about how the industry is going to continue to compete with the Part 121 industry and how, can we look at qualification minimums and maintain an appropriate level of safety while balancing all of those external challenges that I think are fairly new for this community.

-Yeah, those are good questions, Rob. I didn't go into a lot of detail as far as there are pilot shortages, more so we are seeing in the fix wing end. So, we have put out and it's in the standards currently, risk tools, like an example of things that you could use. If you have a pilot who doesn't quite meet the hours that we're requiring, they meet the FAA hours, but not ours. If you have a risk tool, you could use something like this adapted to your own practice. And submit it and we have an aviation event Committee that looks at it and will give recommendations. You don't have to take those recommendations but it's something that might help you to hire pilots that have the proper experience but maybe not the hours. And then we ask that when we come back three years later, we'll look at that and see did you include that in your quality management process to see were those pilots adequately

trained? Did they perform? What was their performance level? And that kind of thing to look back on and see when you hired pilots that less had less than the hours.

It's also an interesting question because we don't always have enough pilots to do site visits. We have to judge that very carefully because we try to send a medical and a clinical and an aviation person on site visits. If it's a reaccrediting program that has really very minimal issues with aviation, we'll send two nurses usually. But if it's a new program or a program that we've seen issues in the past, then we will try to send a pilot with the nurse and sometimes there's a team of sometimes five people going out to look at all the bases and talk to all the people. I don't know if that helps you with your question.

-It does. Thank you.

-Alright, thanks, Elaine. Ben.

-That just added to Rob's, I mean, Rob, you identify a really challenging thing for our industry and it's a big discussion. Amongst all of us that how do we recruit and retain pilots. And I think you know, a big part of that ultimately will come back to pay reimbursement and how as an industry get paid so that we can compete competitively with the dollars that the 121 ones are able to offer. Until we can do that it's going to be a challenge but lowering the standards of the pilots that's then you run into the safety piece, not that hours always equate to safety, right? We all know 7,000 hour pilots that aren't particularly good and 1,500 hour pilots that are great. So, but you highlight a significant challenge that I think it would be good for us to discuss as a Subcommittee.

-Thanks, Ben.

-Alrighty, any other comments for Nolan and what he's laid out? Any other questions since we are a little bit ahead. Alright now Dr. Hinkley.

So with regard to improving service reliability in poor weather. I don't know if the FAA would have anything to do with what I'm about to say, but the biggest game changer for, a HEMS program being available during poor weather, is whether or not they have the opportunity to go by ground. And it seems to me that there currently is not sufficient financial incentivization to do that such that most programs do not do it. But at my program, each of our bases, we have what we call a fly car. And, if the weather is not flyable. We can do what we call air-by-ground transport and rendezvous with the patient whether it's at a hospital, at a firehouse, or at an airport. We don't rendezvous on the side of the road, but we find a safe place to rendezvous. Then we can go with an EMS crew by ground with that patient wherever they need to go. Of course we bring all our clinical equipment along. And I would like to see the Committee potentially discuss making a recommendation on how we can

better financially incentivize that behavior. My understanding is that when my program does that, and we transport the patients in somebody else's ambulance not owned by my program or my hospital. We don't get paid a dime for it. And sometimes those transports are three or four hours, but they can totally be lifesaving.

-That's really good. Jason?

-Yeah, I think the ground piece is definitely something I think we need to talk about not just as something Bill is mentioning here. From a reimbursement perspective but there's also an issue with, which is actually getting ground units available to assist sometimes, and actually more and more by the day. As we move forward, we're running into a lot of issues especially in rural places where the ground assets are few and far between and the communities are faced with the choice about giving up a ground truck for several hours to move one patient and leaving their community without coverage. So I think, you know, that's probably a robust discussion for us to have about direct impact that was mentioned in terms of how we provide service and then how that critical service is going to continue to support connecting air medical with some of the facilities that don't have immediate access either due to helipad or in the case of a fixed-wing transport or weather. So, I think we definitely need to spend some time there. Tom, brought up some great points that I think we need to dive into a little bit. It would probably do as well to meld a little bit of that with a comment about some previous work done by the Rotecraft document protection working group and some other FAA committees and previous safety studies that have been done. There's been a lot of great work already invested and some great ideas and recommendations that have come out. We should probably go through those and see which ones haven't actually been actioned and are something to revisit at this point in time before you reinvent the wheel in some places.

-Thanks Jason. Tom?

-Yeah, echoing Jason, the ground in rural areas is really frail to falling apart. I think we did a big study in Maine and the Blue-Ribbon Commission said it was on the cliff. We do as we go forward. I mean reimbursement is part of this discussion. It was certainly recommended. by the NTSB to HHS to think about reimbursement. We know the ground critical care was the single biggest loser in the ambulance fee schedule. And basically almost overnight, every rural ground critical care hospital-based service basically ended because of the reimbursement. So, we are going to, I think as we do recommendations, some of these things have some crossover as to how this is going to get done going forward.

-Thanks, Tom. Jim, you had your hand up.

-Yeah, I guess I'll pile on at this point. In my comment, reiterating Jason and Tom, as well as really connecting it back to our morning conversations with Joe House and talking about triage and I think there were a couple comments made about being sensitive to how we box certain things and when we think about acuity and utilization because the reality is while it's tangential. To this conversation, it is impactful when you think about the utilization of air ambulance resources today when you have communities that don't have resources, it was mentioned to take an asset out of service for six hours versus flying it in the past that might not have been the case, but today it is very much the case in many of these communities. And I would remind our group that it's not necessarily out of convenience either when you think about a rural critical access hospital with six beds and that patient who may or may not have five years ago necessitated an air ambulance, but by the fact that they're tying up those resources for 12 plus hours people are now becoming more likely to use our services, whether that's right or wrong I think that's part of this discussion.

So it's difficult to say because we can't solve every problem as it relates to the prehospital environment but it's important for us all to remind not only us but the public of the complexity of this and how all of these things do connect to one another.

-Thank you, this is a really good discussion. And I think it's good to be able to have this at the forefront as the Subcommittee is meeting and as we meet back together. We're just slightly ahead of time but I am going to move on if there's no other discussions on this topic.

Okay, so thanks again, Nolan. And the Committee for the rich discussion on flight safety.

We're now going to move on to our final speaker, Dr. Sean Michael, to facilitate the clinical standards discussion. Dr. Sean Michael is an actively practicing emergency physician with a dual board certification in clinical informatics.

He serves as the regional chief medical officer in the Centers for Medicare & Medicaid Services in the Denver location focusing on a crosscutting implementation of CMS program and policy. He also helps lead CMS agency-wide work on emergency care, including EMTALA, emergency department boarding and crowding, emergency medical services, acute behavioral healthcare, and emergency care of older adults. Please welcome Dr. Michael, thank you.

-Thank you so much. Good afternoon to everybody and thank you for the opportunity to join you today. Really appreciate your service on the Committee and thank you for the incredible work you're all doing every day in your day-to-day role serving our communities also.

Our goal for this last session really is to level set around the clinical standards and the statutory charge to this Committee that relates to those. My hope is to build on the excellent content that's been presented all day and the conversations you've already had make use of the incredible depth of expertise of the Committee members and sort of continue what Nolan just facilitated a moment ago about what might be possible around flight standards this time with an eye toward clinical standards.

By the end of the 30 minutes here, we certainly will not have a comprehensive sense of what the Committee might contemplate recommending or reporting to Congress with respect to clinical standards, but my hope is that the discussion or through the discussion the Committee can help identify some priority topics and work with a clinical standard Subcommittee in their upcoming discussions to identify what major gaps there may be or what else you may want to explore more, hear more about to support your work in the Subcommittees work.

By way of additional bit of introduction, you know, Jeff mentioned my background role, CMS, was just a joy to get to support all of you in this in part because I'm also a fixed-wing pilot and also had an EMS and fire rescue career prior to med school including the privilege of working as clinical staff for Jana in a program that she led years ago. So now part of my responsibility at CMS is really working across all of our program and policy areas, especially around clinical issues that don't fit neatly into one place. As you all know, and as we talked about today, emergency care and acute care and patient transport don't have a single home with any one federal agency. And they don't have a single home within EMS or within CMS, sorry, either.

As many have said today. I'm the landscape is really complex and so part of my role, for example, includes helping represent CMS within the federal interagency committee on EMS and working internally to understand how we can better integrate and align our work.

So hopefully we can use some of that to make sure that we can provide you with the additional resources that you need as your deliberations continue.

We can go to the next slide and we'll look at the charges from the statute. There's already been a lot of good conversation about these today, but the clinical standard Subcommittee is tasked with identifying potential statutory and regulatory and guidance and clinical standards gaps that are applicable to air ambulance clinical standards and quality and specifically addressing qualifications for different clinical capability levels and tiering, patient safety and quality standards, and clinical triage criteria for air ambulances. We'll talk about these in a little bit more detail and then have a conversation at the end.

In contrast though to what we heard with the flight safety regulatory environment that Nolan described so well, there really isn't an established federal regulatory structure for authority for air ambulance clinical standards. Aa you know, Tom Judge mentioned the history of why that is a little bit earlier also and we get into that in a minute.

As we heard from our experts earlier today, clinical standards and quality measurement are much more diffuse with voluntary accreditation programs and they interdigitate with state licensure and regulatory schemes, but not so much at the federal level. Most of the CMS regulatory authorities to establish clinical standards are really derived from our payment stewardship role in ensuring that public funds are spent wisely to advance high-quality healthcare. As Dr. Klein mentioned earlier, CMS had outlays of about $1.48 trillion dollars in fiscal year 2023 so we represent about 14% of total federal spending by comparison defense outlays where $726 billion. About a 160 million Americans receive healthcare coverage through Medicare, Medicaid, and health insurance marketplaces that CMS oversees.

As Commissioner Arnold mentioned earlier today, the coverage in the payment landscape is orders of magnitude more complex and heterogeneous than even just that. But nevertheless, as an agency, we have a critical stewardship role to ensure that all those public funds are spent in a way that advances health and healthcare of the high quality that the American people expect. But like any executive branch agency, we're authorized by Congress to act only within the statutory authorities granted to us. And so generally speaking, CMS doesn't have an existing statutory authority to directly pay for most discrete clinical services in EMS or out of hospital care or during transport. Because the statute creating Medicare in 1965 envisioned ambulances as a method of transportation as Tom said earlier, not as a provider of medical services in the way that a physician or a hospital might be.

Then Congress established the ambulance fee schedule in 1997 as one way to recognize the variety of care capabilities provided by EMS and different ambulance platforms you might say but we still fundamentally have to work within the statute in current state. CMS doesn't really have a clinical standards program for ambulances, air or ground, like we do for hospitals or nursing homes or lots of other different provider types. Because Medicare coverage for those other provider types is very differently defined in the Social Security Act compared to how it defines ambulances, which are legally a transportation supplier, because mostly they were in 1965. Most of our statutory authority to create conditions of participation, which came up earlier for hospitals for example, comes from language in legislation that says and meets such other requirements as the Secretary finds necessary in interest of health and safety of individuals who are furnished services at that institution. And so we then use notice and comment rulemaking, public rulemaking, to define what those specific standards are. And then David and his team build interpretations and

guidance and training to show surveyors how to assess compliance with those standards. David and I coordinated our outfits today, by the way. We have some other examples of other regulatory programs that sort of fit a little bit of a different statutory scheme that we could look at also to the clinical lab regulatory scheme in the US that was created under the Clinical Laboratory Improvement Act (CLIA).

The SAMHSA, Substance Abuse Mental Health Services Administration, has authorities related to opioid treatment program standards that are not directly sort of attached to Medicare funding, for example. I mean, there's examples of other clinical standards programs attached to various statutes outside of just Medicare payment. But that's sort of the most common. And so the discussion highlighted earlier this Committee is charged with making reports and recommendations to Congress.

And so you don't necessarily need to imagine only authorities that exist today. But I say all of that to illustrate some different models that do exist which the Committee and the Subcommittee might look at because it's important to recognize that compared with the safety tasking there is a far less developed federal regulatory landscape on the clinical side in current state today. We can go to the next slide.

We'll look at the three different bullet points that are at the end here. We've done some prep work to describe in general terms some of the considerations the Committee and the Subcommittee might want to evaluate. For the capability levels and tiering, those include specialty care versus what you might consider more general critical care. The regional certification requirements and other cross-state regulatory rules that sort of already exist specialty certification requirements, scope of care for people involved, crew composition. That might include considering what things we've heard about already today, you know, high risk OB, ECMO, balloon pop, neonatal transplant, other types of specialized transport capabilities. Understanding the multi-state nature that the folks have talked about already today about the existing regulations and what future regulations might impact there.

As came up in the last conversation, how the current ambulance fee schedule tiering interacts with future recommendations that you might make.

The fee schedule for air transportation, as folks here know, is a little bit different than ground. But the fee schedule does provide sort of a framework that informs Medicare reimbursement, at least in fee-for-service Medicare that is important to sort of consider here. You can look at the next slide.

That's the next very broad umbrella around patient safety and quality standards. In terms of that, as you all know, and we spoke about this earlier, there's obviously considerable work in the space already, although not really in federal government or federal programs. That

might include looking at infection prevention and control, communication, coordination with receiving and sending medical facilities to that matter. The actual standards of clinical care in the field or in transit, opportunities, to look at outcomes and accountability for outcomes and attribution, and as Ron mentioned earlier, the issues around how to do risk adjustment there, readiness capabilities also. But I think that clinical data interoperability and reporting might fall into this tasking also. There's a great conversation about Nemsis obviously and data collection or sharing or training requirements, service shopping or reasons for flight declines, or consequences of declines or patient experience, patient safety events, fatigue management came up earlier today. In addition to the sort of patient outcomes and quality. So it's a very broad sort of umbrella that that you have to work with here. And it could also include integration with safety management systems, crew resource management systems, AMRAM, other training standards and also the interaction between flight safety standards and how that impacts patient safety as well.

On the next slide are the clinical triage criteria. And so I think you could explore questions here about existing and future air ambulance clinical use criteria. That's come up a bit as well. The tracing systems that are currently available and currently used, how those are implemented, over and under triage, standardization opportunities around that. And really evaluating who has responsibility for ensuring that the triaged patient care needs and the requested air ambulance service response capabilities are sufficiently matched and what impact these matches have on patient outcomes, how to effectively apply standards. Whether there should be clinical standards around changing from ground-to-air or air-to-ground under differing conditions, geography, flight conditions changing, the error by ground incentives dilemma that Dr. Hinkley mentioned just a few minutes ago would fit in there. Many potential questions I think could be embedded in this part of the charge also.

We can tee up the discussion on the next slide. I think, you know, none of the elements in the Committee's charge are starting from scratch obviously and as we've heard all day. There's lots of existing ideas and novel ideas to integrate here. As folks have alluded to already, the Committee isn't necessarily charged with actually developing every single detailed clinical standard or triage criterion or tiering in the course of its work. But I suspect it will be important to at least consider the structures and the frameworks and the processes, the levers and the incentives that will be applicable in formulating your deliberations and your recommendations. Hopefully, Mr. Chairperson, we can tee up a conversation about a few things. One what questions the Committee has about the tasking. Two if there's major clinical domains that are missing here. And it'd be helpful to hear if there's other pieces of information that the Committee members want to know about to help inform deliberations or other thoughts that the Committee has for information that we can help provide.

=Yeah, thanks. Dr. Michael, I appreciate that. And thanks for the great overview. I think this is a good segue. I invite all the members to come back on camera so that we can have a discussion about this and is there things for the discussion for this Committee.

Any other questions? I think you did such a great job, Dr. Michael, that people are speechless, right?

-There were a couple of things that, that came up about conditions of participation, how that works earlier.

-Yeah.

-Hopefully, that addresses some of the background for that. But obviously there's a lot of expertise of Committee members on various factors that end the billing and sort of payment facets as well. You're well suited with folks who are on the Committee with expertise in this but if we can help provide technical assistance from folks within CMS or any other places, we're always happy to do that as you're deliberating over time.

-Well, and I think that was really, really good to be able to talk about how, it was really an overview of an ambulance. I think Tom mentioned this and you did too is that ambulance was department transportation it was a mode of transportation and no one at that time when they created this thought that we would be delivering high quality medicine in the back of that vehicle. So I think that it was really good to be able to do this. I guess Mike, I'm curious is that we've made incremental pieces, like with an ambulance fee schedule, but is there something that has to happen in Congress to be able to change the statutory ways to be able to view us differently. I'm just curious just asking.

-I think the direct answer from CMS on that is the yes, we operate within the bounds of statute. It's not our role. I'm not here today to advocate for a particular position and it's not our role as an agency to sort of make a recommendation to Congress. That's why the FACA exists in the process. But yes, to have an authority for CMS for example to be able to think about paying differently in the Medicare program would require different statutory authorities or guard rails to be changed.

To have, you know, people ask us all the time with respect to general EMS issues. Can't CMS in some way identify EMS as an essential service or do something with sort of the payment structure for EMS to make up for some of these really significant differences in cost and resource availability and fixed costs outlay all the sort of issues that have come across the conversations already. And the direct answer there is we don't have an authority to do that. We really just work as, you know, as an executive branch agency we work within the bounds of what Congress permits for us. But it is within the scope of the Committee to

deliberate and make recommendations to Congress. And so, as you all look at what those existing structures are and what a future set of structures could look like, it doesn't have to be CMS that's the agency, right? Federal executive branch agencies could potentially have authorities in a future scheme based on what Congress does and what you all might recommend.

-Thanks. Alright, Tom.

-Sure, and thanks, Sean, for that. I think it's important. One of the other parts of the NSA, which is really the first step of this discussion, is the cost reporting requirement. That hasn't really come into play yet. I know we've done a lot of work with the CMS contractors looking at what that may look like. We're still a couple of years away from. Get the cost report you know the first real information run cost reporting on the ground side. So I think that those are important pieces in a broader discussion. EMS is only an essential service in 16 states of the country. So, in most of the states of the country, EMS is not essential. It's not thought of the way that you think about police or fire or any other essential service and that's where we get into this cobbled funding. We have grace on this Committee. I think that that's one of the pieces that that we ought to be looking at more broadly is how do we think about this at the state level?

I know we've done a lot of work in Maine, that EMS is now an essential service and how the state is investing in that as a result. That could be another sort of avenue that we go down to begin to think about some of these questions.

The other piece that I had, and you might want to do as you get your Subcommittee going Jeff is to do a symposium. We do one on the future of our medicine every year. In this last year we did a big piece around patient selection and triage and had Stephen Thomas and Jacky stocking both did really deep presentations on the evidence base for triage and what we actually know about this.

I think that both of those presentations and presenters would probably be really valuable for the Subcommittee to hear. I shared some of the slide stuff with Michelle briefly, but I would suggest getting a hold of them because it really is what is the evidence base that we know about triage.

-Alright, great. That's a great idea. And yes, please send that and get that information over to Michelle and we can use them as resources. So, thank you.

-Okay, anyone else, for discussion of clinical standards?

Okay, I think that we're getting towards the end of the day here. So, I appreciate that. I will move us on to that if there's no more discussion for the group. Next slide.

I think it comes to me. So, we're at the final part of the day and really would like to be able to bring up your final reflections and any recommendations for future discussion topics.

I think, Tom, you mentioned it right there at the last minute of what we might be able to talk about, but I want to be able to bring this up just to be able to ask, how did it go? Are there things that we can improve on? Then we could go into any sort of other recommendations for future discussion topics.

-Nice job, Jeff, it was well organized, and you kept a tight ship, so I'll give that feedback.

-Thanks.

-Yes, I concur. I mean, it was very well done, very well organized. And I really appreciate that folks stuck toward the time. It was very helpful to keep us moving and efficient. I think we all had some really great, discussion and I'm really excited about the Committee at large and the work we're going to do with just everyone's perspective. So great job with that. And again, good to have the different perspectives really appreciated, you know, as a patient activist and advocate. Oftentimes that patient voice is not always appreciated to the level that I think it should be. But that was not the case here. It was absolutely valued. And so, I really think that this collective group will have a much more rich report that is pushed out to Congress, because of it valuing of perspective, so really, really well done.

-Grace? I will concur. I think this is really well organized and really helpful. You know, as I was kind of reflecting on the day and a lot of the comments. There are comments and topics that are sort of directly related to our statutory requirements and then there's like all the stuff that facilitates that happening. I think most about financing but there are a number of other things. We might want to think about as you're structuring the conversations, how we have conversations that are very focused on the statutory requirements and then we have probably more generic kinds of discussions about like there needs to be a financing mechanism that supports this and here are the kinds of things. Or you know, I can imagine that the specific recommendations might be a little broader in those categories but are so important.

So, you might want to just think about how we can sort of divide up, the very concrete, you know, clinical standards. There's a bulleted list that's in the statute and then some of the supporting concepts or structures that either are challenges or threats to the things that we would recommend or that can be supportive.

-Thanks. That's really good comment. Anyone else?

Okay. Oh, Dr. Hinckley.

-Thanks, Jeff. And thanks for all your work today on keeping us on task and on schedule. It's a huge honor to be a part of this group. I've learned a ton today from all of you. As a guy who shows up in a flight suit six or seven times a month. I'm very hopeful about what this Committee can accomplish. In finally creating some true financial incentivization for both aviation quality and clinical quality that in the past has not really been there. It's sort of an overwhelming task, but I'm reminded of all of the work that so many people have done that we can build on. People like Eileen and CAMTS, people like Tom and ACT., people like Stephen Thomas and Jackie Stocking, that Tom just mentioned a few minutes ago. They have done a lot of work that we are not going to have to recreate the wheel. thank you very much.

-Great, thank you.

Okay, well, I'm just going to go over our future meeting dates, which were several hours ago, but February 18th we will have our next meeting, which is 10 am to 5 pm Eastern virtual and then May 8th, 10 am to 5 pm virtual and then agendas for future meetings will be made public. This is the email below for everyone to be able if you have any additional comments about today's meeting. My final comments and are really I just am really proud, and I thought the discussion was incredible and I also echo what Dr. Hinckley just said there that for someone that has had a long career in air medical that this is a really amazing time to be able to make some really great changes. And this is the group that can help do that. I'm really excited for us to be able to be able to come together to be able to look at what the tasks are that we need to deliver on and then deliver recommendations to Congress. Thanks.

Nolan, you have your hand-up, before I move into how you register for the next meeting. Nolan, go ahead.

-Yes, sir. I like to compliment also on the running of the Committee today, but I also like, I think we'd be remiss if we didn't thank the people behind the scenes today. Ali and Michelle, and Nicky, they've been great helping me on the aviation Subcommittee side at least and I wanted to say that publicly if they happen to have a boss or whatever there today, they've done an awesome job and I appreciate them.

-Absolutely, I totally agree. The amount of meetings that we had prior to this meeting was a lot, but I think, the organization, you can see the product that we were able to be able to put

up. Thanks everyone and thank you to the entire team, Michelle and Ali. Just really good stuff. David, do you have anything else to be able to add as we close out?

-I think I have the last part, Jeff, so unless there's anything.

-Okay, right as I'm going off my run of show you're right there so just remember that there is a place to be able to register for those that are in the public to be able to register for the next meeting and I'll just hand it right over to you. David.

-Thank you. I've had the easiest job today of. Welcoming you and bringing you back from breaks and I have the best role too in adjourning this meeting, but I do want to thank all of you for your passion and commitment as the designated federal official I could tell you that I've sat through as many of you have many federal meetings. Most lack the passion and commitment that you all have displayed today. And so, thank you for that. I think this Committee is going to do an excellent job of safeguarding the values that you all hold dear and provide recommendations to make them better.

As Jeff said, and again, kudos to Jeff and sharing this and echo the kudos to MITRE and the folks who have really done so much work literally behind the scenes on this. We will reconvene on February 18th. At this point, it's my pleasure to adjourn this meeting. Thank you so much.