



**CMS 2010 Tri-Regional Plan Compliance Conference**  
*Dallas Hilton Lincoln Center, May 19-20, 2010*

**A MOSAIC of More: More insight, More answers, More compliance...**

Verbatim Transcript  
Compliance Plan Requirements and Evaluating Effectiveness  
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**Part 1**

>> COMPLIANCE PLAN REQUIREMENTS  
AND EVALUATING EFFECTIVENESS.

OUR PRESENTER  
IS MICHELLE TURANO.

MICHELLE IS DEPUTY DIRECTOR  
OF THE PROGRAM COMPLIANCE

AND OVERSIGHT GROUP  
IN BALTIMORE.

I'VE KNOWN MICHELLE AND WORKED  
WITH HER, AND I THINK YOU'RE

IN FOR A TREAT.

PLEASE HELP ME  
WELCOME MICHELLE.

[APPLAUSE]

>> GOOD AFTERNOON, EVERYBODY.  
I'M MICHELLE TURANO.

AS JULIE SAID, I'M ONE OF  
THE DEPUTY GROUP DIRECTORS

IN BALTIMORE.

THANK YOU FOR COMING



BACK AFTER THE BREAK.

I KNOW WE'RE RUNNING OVER  
A LITTLE, BUT I PROMISE EVERYONE

WILL GET OUT OF HERE ON TIME.

I ALSO JUST WANT TO SAY THANK  
YOU TO THE DALLAS, ATLANTA,

AND KANSAS CITY REGIONAL  
OFFICES FOR PUTTING THIS EVENT

TOGETHER AND FOR INVITING  
ME HERE TODAY.

I THINK IT'S BEEN  
A REALLY GREAT EVENT SO FAR.

SO WHAT ARE WE GONNA  
TALK ABOUT TODAY?

COMPLIANCE PLANS.

SPECIFICALLY, I WANT TO TALK  
ABOUT THE NEW COMPLIANCE PLAN

REQUIREMENTS WHICH WERE  
RECENTLY ENACTED IN REGULATION

THAT WAS PUBLISHED  
ON APRIL 15.

AND THEN I ALSO WANT TO FOCUS  
TODAY ON ONE ASPECT THAT WAS

ONE OF THE CHANGES IN THE  
REGULATION AND THAT IS

MEASURING EFFECTIVENESS  
OF COMPLIANCE PROGRAMS,

WHICH I GUESS  
IT IS SOMETHING NEW.

HAVING A COMPLIANCE PROGRAM OR  
A COMPLIANCE PLAN HAS ALWAYS

BEEN A REQUIREMENT.

THE SLIGHT SWITCH OR FOCUS  
ON EFFECTIVENESS, HOWEVER,

IS SOMETHING THAT'S NEW.

BEFORE WE GET INTO THE  
WEEDS OF THE PRESENTATION OR

OF COMPLIANCE PLANS, I WANT  
TO TAKE A FEW MINUTES TO TALK

ABOUT BASICS, AND I'LL DO THAT  
OVER THE NEXT COUPLE OF SLIDES.

THERE ARE 7 ELEMENTS,  
INDIVIDUAL REQUIREMENTS

OF COMPLIANCE PLANS.

THESE ARE NOT A CMS CREATION.

THEY DERIVE FROM THE OIG  
SENTENCING GUIDELINES

THAT WERE PUBLISHED  
SEVERAL YEARS AGO.

HOWEVER, WHILE THEY'RE NOT A  
CMS CREATION, THEY ARE A CMS

REQUIREMENT AND WE WILL BE  
GOING OVER EACH

OF THE 7 ELEMENTS  
IN PAINSTAKING DETAIL.

SO I'M GLAD EVERYBODY GOT  
THEIR COCA-COLA BEFORE WE

START TO DO ALL THAT.

THE SECOND BULLET HERE--THIS IS  
THE PURPOSE OF YOUR COMPLIANCE

PLAN: TO PREVENT, DETECT,  
AND RESPOND TO VIOLATIONS

OR ISSUES OF NON-COMPLIANCE  
WITHIN YOUR ORGANIZATION.

YOUR COMPLIANCE PLAN ALSO  
SHOULD REFLECT OR HIGHLIGHT

THAT THERE ARE MEDICARE

SPECIFIC PROVISIONS

AND REGULATIONS THAT NEED  
TO BE COMPLIED WITH.

I'M GONNA DO THIS NEXT  
PART VERY QUICKLY.

I JUST WANT TO RUN THROUGH  
THE 7 ELEMENTS

OF A COMPLIANCE PLAN.

AND LIKE I SAID,  
DON'T WRITE THEM DOWN.

THEY ARE THERE AND WE'LL  
GET TO THEM IN DETAIL.

BECAUSE REPETITION IS THE  
BEST WAY TO LEARN SOMETHING,

THE FIRST ELEMENT OF A  
COMPLIANCE PROGRAM IS THAT YOU

HAVE POLICIES AND PROCEDURES  
AND A STANDARD OF CONDUCT THAT

REFLECT YOUR COMMITMENT TO  
COMPLYING WITH MEDICARE LAWS

AND REGULATIONS.

NUMBER 2, YOU HAVE TO HAVE  
DESIGNATED A COMPLIANCE

OFFICER WITHIN  
YOUR ORGANIZATION.

ELEMENT 3, YOU ARE REQUIRED  
TO HAVE EFFECTIVE TRAINING

AND EDUCATION FOR ALL  
EMPLOYEES AROUND COMPLIANCE

IN YOUR ORGANIZATION'S  
COMMITMENT TO COMPLIANCE.

NUMBER 4, SORT OF DERIVING  
FROM THAT, THAT YOU'RE

REQUIRED TO HAVE EFFECTIVE

LINES OF COMMUNICATION.

NUMBER 5, YOUR ORGANIZATION  
NEEDS TO HAVE WELL PUBLICIZED

DISCIPLINARY STANDARDS  
FOR WHEN COMPLIANCE

VIOLATIONS OCCUR.

YOU NEED TO HAVE A SYSTEM OF  
ROUTINE INTERNAL MONITORING

AND AUDITING.

AND THEN FINALLY, THE PLAN  
NEEDS TO HAVE OR ENABLE YOUR

ORGANIZATION TO HAVE A PROMPT  
RESPONSE TO DETECTED OFFENSES.

AND WE'LL GET INTO THAT IN  
MORE DETAIL IN A MINUTE.

YOUR COMPLIANCE PLAN  
NEEDS TO DEMONSTRATE YOUR

ORGANIZATION'S COMMITMENT NOT  
ONLY TO HAVING THE PLAN OR

THE PROGRAM, WHICH IS AN  
INFRASTRUCTURE, A FRAMEWORK

OF COMPLIANCE FOR YOUR ENTITY,  
BUT IT REALLY NEEDS TO BE ABLE

TO DEMONSTRATE THAT YOUR  
ORGANIZATION HAS A CULTURE

THAT IS COMMITTED  
TO COMPLIANCE.

AND THAT IS MUCH HARDER  
TO DEFINE OR TO DESCRIBE,

BUT I THINK AS WE TALK  
A LITTLE ABOUT IT,

IT WILL BECOME MORE CLEAR.

YOUR COMPLIANCE PLAN OR  
COMPLIANCE PROGRAM--AND I'M

GONNA SAY THOSE BACK AND  
FORTH THE WHOLE PRESENTATION--

MUST REQUIRE ENGAGEMENT AND  
COMMUNICATION AMONG NOT ONLY

YOUR EMPLOYEES, YOUR  
COMPLIANCE OFFICER,

YOUR ENTIRE STAFF, BUT ALSO  
THE MOST SENIOR EXECUTIVES

WITHIN THE ENTITY AND  
YOUR GOVERNING BOARD.

AND IT REALLY IS THE VEHICLE  
THAT DEFINES THE EXPECTATIONS

FOR YOUR EMPLOYEES FOR WHAT  
ETHICAL AND PROPER BEHAVIOR IS,

SPECIFICALLY AROUND  
THE MEDICARE LINE OF BUSINESS.

MOVING ON.

ONE OF THE THINGS JIM KERR  
MENTIONED THIS MORNING WAS

THAT PART OF THE, I GUESS,  
REASON WHY YOU WOULD WANT TO

HAVE A GOOD COMPLIANCE PROGRAM  
OR A COMPLIANCE PLAN IN PLACE

IS THAT YOUR ENTITY NEEDS TO  
BE PROACTIVE WHEN IT COMES TO

ISSUES OF NON-COMPLIANCE OR  
FRANKLY, SIMPLY COMPLYING

WITH LAWS AND REGULATIONS  
SO THAT CMS DOES NOT

HAVE TO BE REACTIVE.

AND THAT'S CERTAINLY  
THE PREFERRED POSITION.

YOUR COMPLIANCE PLAN NEEDS  
TO IDENTIFY RISKS WITHIN YOUR

ORGANIZATION--AND THEN AGAIN  
I'M GONNA SAY THIS PHRASE

SEVERAL TIMES--IT NEEDS TO  
ENABLE YOU TO PREVENT, DETECT,

AND RESPOND TO VIOLATIONS  
WITHIN YOUR ORGANIZATION.

WHY ARE COMPLIANCE  
PROGRAMS IMPORTANT?

WELL, NUMBER ONE, THEY  
ARE REQUIRED FOR YOU TO

CONTRACT WITH CMS.

IT IS A REQUIREMENT  
IN YOUR APPLICATION.

I THINK JENNIFER SHAPIRO MAY  
HAVE TOUCHED ON THAT EARLIER.

COMPLIANCE PLANS AND  
COMPLIANCE PROGRAMS WILL BE

AUDITED BY CMS DURING 2010  
AND THE 2011 AUDIT YEAR.

AHEM. PARDON ME.

SO NOT ONLY ARE YOU REQUIRED  
TO HAVE THEM,

AND I KNOW THAT  
THEY ARE--

HMM. I WONDER IF SOMEONE ELSE  
DRANK OUT OF THAT ALREADY.

[LAUGHTER]

THAT OPENED  
A LITTLE TOO EASILY.

THERE WE GO! OK.

SORRY ABOUT THAT.

OK. THANKS VERY MUCH FOR  
INDULGING ME THERE.

ANYWAY, SO YOU'RE REQUIRED  
TO HAVE A COMPLIANCE PROGRAM.

I THINK I'VE SAID THAT  
A COUPLE OF TIMES.

BUT AGAIN, WE WILL BE AUDITING  
FOR COMPLIANCE PLANS

IN 2010 AND 2011.

AND IF YOU ASK ME,  
A SUCCESSFUL COMPLIANCE PROGRAM,

OUR NEXT BULLET HERE,  
THIS IS THE ENTIRE GOAL

OF HAVING A COMPLIANCE PROGRAM,  
AND I'VE SAID THIS ALREADY:

TO PREVENT, DETECT--  
HELP YOU PREVENT, DETECT,

AND RESPOND TO OFFENSES THAT  
ARISE WITHIN YOUR ORGANIZATION

SO THAT YOU ARE ABLE TO HANDLE  
THEM AT A LOW LEVEL BEFORE

THEY BECOME A MORE SIGNIFICANT  
ISSUE AND CMS HAS

TO INTERVENE.

SO A LITTLE MORE.  
WHY ARE THEY IMPORTANT?

WELL, A COMPLIANCE PROGRAM IF  
IT'S DONE WELL OR IF IT'S DONE

POORLY--YOU COULD SEE BOTH  
ENDS OF THE SPECTRUM HERE--

CAN HAVE AN IMPACT ON A VARIETY  
OF ASPECTS OF YOUR ORGANIZATION

AND SORT OF HOW  
IT IS PERCEIVED.

MOST IMPORTANTLY IS THE  
IMPACT ON BENEFICIARIES.

AS JIM MENTIONED THIS MORNING,  
CMS RECENTLY HAS TAKEN--

AND I THINK I'LL SAY THIS  
AGAIN LATER--2 MARKETING

AND ENROLLMENT SANCTIONS IN  
THE PAST COUPLE OF MONTHS

AND ONE CONTRACT TERMINATION  
SPECIFICALLY AROUND ISSUES

THAT WHERE THERE WERE  
COMPLIANCE PROGRAM FAILURES.

AND IF YOU WERE TO READ THE  
NOTICES PROVIDED TO THOSE

ORGANIZATIONS, COMPLIANCE  
PLANS OR A LACK THEREOF

ARE SPECIFICALLY HIGHLIGHTED  
IN THOSE NOTICES.

SO WE'RE NOT IN A PLACE WHERE  
WE MAY HAVE BEEN IN THE PAST

WHERE YOU COULD HAVE A VARIETY  
OF VIOLATIONS THAT WOULD LEAD

YOU TO A SANCTION OR A CONTRACT  
TERMINATION

AND "OH, BY THE WAY,  
YOU SHOULD PROBABLY HAVE

A COMPLIANCE PLAN  
ON TOP OF THAT."

COMPLIANCE PROGRAMS,  
OR LIKE I SAID, A LACK THEREOF,

ARE NOW SORT OF DRIVING  
THESE ACTIONS.

SO THEY'RE NO LONGER ON  
THE PERIPHERY ANYMORE.

IT REALLY IS A FOCUS, AND MY  
POINT ABOUT BENEFICIARY IMPACT

IS THAT IN THESE ACTIONS  
THAT WE'VE RECENTLY TAKEN,

IT'S BECAUSE THERE HAS BEEN A  
BENEFICIARY IMPACT OR FAILURE

OF A COMPLIANCE PLAN THAT LED  
TO BENEFICIARIES NOT HAVING

ACCESS TO DRUGS, BENEFICIARIES  
NOT HAVING ACCESS TO SERVICES.

WHEN CMS OBSERVES THAT,  
WE'RE REQUIRED TO TAKE ACTION.

ADDITIONAL IMPACTS TO  
YOUR ORGANIZATION WOULD BE

A FINANCIAL IMPACT, OBVIOUSLY,  
FINES OR PENALTIES OR

AN INABILITY TO ENROLL  
OR MARKET YOUR PRODUCT.

AN OPERATIONAL IMPACT,  
I CAN TELL YOU FROM WORKING

WITH SEVERAL--ALL, ACTUALLY,  
ALL OF THE PLANS THAT HAVE

BEEN SANCTIONED OR FINED IN  
THE PAST COUPLE OF YEARS.

WHEN THAT SORT OF ACTIVITY  
HAS OCCURRED WHEN THERE'S BEEN

A SANCTION OF ANY KIND IN  
PLACE OVER THE ORGANIZATION,

I CAN TELL YOU THAT A  
SIGNIFICANT, A SIGNIFICANT

AMOUNT OF RESOURCES FROM THOSE  
ENTITIES IS DERIVED AWAY FROM

DAY-TO-DAY BUSINESS AND SOLELY  
FOCUSES ON CORRECTING

THE SANCTION AND  
GETTING RID OF IT.

AND SO THAT HAS AN EXTREME

IMPACT ON YOUR OPERATIONS,

YOUR RESOURCES.

IT'S JUST A TOUGH SPOT TO BE  
IN AND I CAN'T OVERESTIMATE

HOW SIGNIFICANT THAT HAS BEEN  
FOR THE PLANS THAT WE'VE

BEEN WORKING WITH.

ADDITIONALLY, OBVIOUSLY,  
THERE'S A REGULATORY IMPACT.

YOU REALLY DON'T EVER WANT  
CMS IN YOUR BUSINESS.

LET'S BE HONEST.

[LAUGHTER]

AND THEN FINALLY,  
A REPUTATIONAL ASPECT OR

IMPACT OF ANY SORT OF  
PUNISHMENT OR FINE.

A RECENT EXAMPLE OF AN ACTION  
THAT WE TOOK, I LEARNED THAT

THIS PARTICULAR HEALTH PLAN,  
THEIR STOCK PRICE DROPPED 20%

OVERNIGHT AFTER THE  
SANCTION WENT INTO PLACE.

SO, AGAIN, NOT A  
SITUATION YOU WANT TO BE IN.

**Part 2**

>> FOR 2010 AND 2011,  
LIKE I SAID EARLIER,

WE WILL BE AUDITING  
COMPLIANCE PROGRAMS.

THEY ARE NOT SORT OF A TAG-ON  
AT THE END OF AN AUDIT.

THIS IS GOING TO BE A VERY

**SPECIFIC FOCUS OF AUDIT.**

I KNOW PART OF OUR TEAM IN  
BALTIMORE WITH SOME HELP FROM

THE OTHER REGIONS ARE DOING  
SORT OF PILOTING A NEW VERSION

OF THIS RIGHT NOW.

WE'VE DONE SEVERAL  
OF THESE ALREADY

AND WE'RE GONNA HIT AS MANY  
PEOPLE AS WE CAN OVER

THE COURSE OF THE NEXT  
COUPLE OF YEARS.

THE AUDITS THAT WILL HAPPEN  
THIS PLAN YEAR FOR 2010

WILL ASSESS COMPLIANCE WITH  
THE REQUIREMENTS THAT WERE

IN EFFECT UP UNTIL--THAT WERE  
IN PLACE FOR THIS YEAR.

SO THE REGULATION THAT WAS  
PASSED ON APRIL 15, WE WON'T

BE AUDITING FOR THOSE NEW  
REQUIREMENTS UNTIL NEXT YEAR

BECAUSE THAT PART  
OF THE REGULATION DOESN'T

GO INTO EFFECT  
UNTIL PLAN YEAR 2011.

SO AS I MENTIONED EARLIER,  
COMPLIANCE PLAN FAILURES

DO HAVE THE POTENTIAL FOR  
SOME VERY SERIOUS ACTIONS

AND RESPONSES ON  
THE PART OF CMS.

AND LIKE I SAID, A LACK OF  
COMPLIANCE PLAN OR COMPLIANCE

PROGRAM WAS REFLECTED IN  
EACH OF THE 3 ACTIONS THAT

ARE HIGHLIGHTED.

IF YOU WANTED TO GO READ  
MORE ABOUT CMS'S ENFORCEMENT

ACTIONS, THERE'S A LINK  
ON OUR WEBSITE,

I THINK GOING BACK  
TO 2006.

VERY FASCINATING  
READING, I'M SURE.

I COULD RATTLE OFF A LIST FOR  
YOU, BUT I DON'T THINK ANYBODY

WANTS TO HEAR THAT.

JIM ALSO TALKED THIS MORNING  
ABOUT WHEN YOU THINK ABOUT ALL

OF THE GUIDANCE THAT COMES  
FROM CMS, AND I KNOW THAT

THERE ARE, I DON'T KNOW,  
HUNDREDS OF THOUSANDS

OF HPMS NOTICES THAT COME  
YOUR WAY ON A MONTHLY BASIS.

IT'S REALLY HARD TO FOCUS  
ON WHAT'S IMPORTANT FROM

A CMS PERSPECTIVE.

NOT EVERYTHING CAN BE THE  
SAME LEVEL OF IMPORTANCE.

SOME PEOPLE WOULD LIKE  
TO CONVINCING YOU OF THAT.

I THINK IT'S IMPOSSIBLE.

SO THIS REALLY IS SOMETHING  
THAT CMS THINKS IS IMPORTANT.

I THINK EVERYBODY THAT'S  
PRESENTED TO YOU TODAY

HAS MENTIONED IT.

AND AS I SAID, JIM  
HIGHLIGHTED IT THIS MORNING.

THE COMPLIANCE PLAN AUDITS--  
AND AS WE GET INTO MORE

OF THE DETAILS ABOUT THOSE,  
I HAD TO INCLUDE MY BOSS'S

FAVORITE PHRASE ON THIS SLIDE,  
WHICH IS THAT IT'S NOT JUST

A PAPER EXERCISE.

PLEASE DO NOT  
"PRINT, POST, AND PRAY."

AND WHAT SHE MEANS BY THAT IS,  
"HEY, CMS IS COMING NEXT WEEK.

WE BETTER BUY A  
COMPLIANCE PLAN."

AND I KNOW PEOPLE  
HAVE DONE IT.

NO ONE IN THIS ROOM, I'M SURE.

BUT I KNOW LOTS OF CONSULTANTS  
WHO WOULD BE HAPPY TO

SELL YOU ONE.

"LET'S PRINT ONE OUT,  
PUT IT IN A BINDER,

"PUT IT ON THE SHELF, AND HEY,  
IF ANYBODY ASKS FOR IT,

WE CAN HAND IT TO THEM."

THAT MAY HAVE WORKED IN THE  
PAST, AND I'M REALLY HOPING

THAT THAT IS NOT WHAT YOUR  
ORGANIZATION WOULD COMMIT TO

MOVING FORWARD BECAUSE CMS IS  
CERTAINLY NOT GOING TO JUST

STOP THERE IN OUR ASSESSMENT  
OF COMPLIANCE PLANS.

CHAPTER 9 IS THE PART OF  
OUR MANUAL THAT INCLUDES THE  
GUIDANCE ON COMPLIANCE PLANS.

IT'S BEEN AROUND FOR A WHILE  
AND IT'S A LITTLE OUT OF DATE,

SO THIS YEAR CHAPTER 9  
WILL BE UPDATED TO REFLECT

THE INFORMATION THAT'S CONTAINED  
IN THE NEW REGULATIONS.

AND SPEAKING OF THE UPDATED  
REGULATIONS, AS I SAID,

THEY WERE PUBLISHED ON APRIL  
15 AND WHILE--I'M GONNA GET

INTO THE DETAILS ABOUT WHAT WE  
CHANGED, BUT IT LOOKS LIKE WE

JUST TWEAKED A FEW WORDS AND  
ADDED SOME DIFFERENT LANGUAGE

HERE AND THERE, BUT REALLY  
IT DOES SORT OF MOVE OUR

EXPECTATIONS FROM SIMPLY  
HAVING A COMPLIANCE PROGRAM

TO HAVING AN EFFECTIVE  
COMPLIANCE PROGRAM.

AND YOU WOULD LOOK AT THOSE  
OR YOU WOULD ASSESS THOSE TWO

THINGS IN VERY DIFFERENT WAYS.

SO WHILE IT JUST SEEMS LIKE  
WORDING CHANGE, IT ACTUALLY IS

A MEANINGFUL SHIFT IN  
WHAT WE'RE LOOKING FOR.

MOST OF THE CHANGES, HOWEVER,  
THAT YOU WILL NOTE

IN THE REGULATION--AND I HAVE  
A COPY IN MY BAG OUTSIDE IF

ANYBODY WANT IT, IF YOU HAVE  
SOME SPARE TIME AND NEED

A LITTLE BEDTIME READING--BUT  
THE CHANGES THAT YOU WOULD SEE

REFLECTED IN THE NEW  
REGULATIONS ARE NOT SURPRISING

IN ANY WAY I DON'T THINK.

IN FACT,  
LOTS OF THE LANGUAGE FRANKLY

HAS BEEN IN  
CHAPTER 9 FOR YEARS.

WE JUST FELT LIKE IT WAS  
SIGNIFICANT ENOUGH THAT IT DID

NEED TO BE REFLECTED  
IN THE REGULATIONS.

AND AGAIN, ONE OF THE  
MAJOR CHANGES IS FOCUSING

ON EFFECTIVENESS.

SOME OF THE SPECIFIC WORDING  
THAT I TALKED ABOUT, LIKE I

SAID, WHILE IT MIGHT SEEM  
SMALL, IT DOES ACTUALLY ALTER

THE REQUIREMENT.

THAT'S REFLECTED HERE  
ON THIS SLIDE.

SO ADOPTING AND IMPLEMENTING  
AN EFFECTIVE COMPLIANCE PROGRAM,

WHICH IS A SWITCH.

THE INHERENT IN A COMPLIANCE  
PROGRAM, THERE DOES NEED TO BE

THE ABILITY TO DETECT,

PREVENT, AND RESPOND TO ISSUES

OF FRAUD, WASTE, AND ABUSE.

WE WORK VERY CLOSELY WITH OUR  
OFFICE OF PROGRAM INTEGRITY,

WHO SORT OF HAS OWNERSHIP OF  
THAT FRAUD, WASTE, AND ABUSE

ARENA, IF YOU WILL, BUT THAT  
IS SOMETHING THAT WE MUST SEE

REFLECTED IN YOUR  
COMPLIANCE PROGRAM.

AND AT A MINIMUM, WHICH IS A  
NEW PHRASE, NEEDS TO INCLUDE

THE 7 REQUIREMENTS THAT  
WE'RE GOING TO TALK ABOUT.

SO ELEMENT NUMBER ONE--  
LIKE I SAID, HERE COMES

THE PAINSTAKING DETAIL PART.

ELEMENT NUMBER ONE,  
THE ORGANIZATION MUST HAVE

POLICIES AND PROCEDURES THAT  
DEMONSTRATE YOUR COMMITMENT

TO ALL APPLICABLE FEDERAL  
AND STATE STANDARDS.

I'M GOING TO APOLOGIZE NOW  
THAT THERE'S A LOT OF TEXT

IN THESE SLIDES, AND I CAN'T  
TELL HOW HARD IT IS TO READ

FROM YOUR PERSPECTIVE OR  
ON THE TINY LITTLE PRINT,

BUT I WANTED PEOPLE  
TO HAVE ALL THE INFORMATION

IN ONE PLACE SO THAT  
YOU DON'T HAVE TO REFER

TO THE NEW REGULATION.

REALLY WHAT WE ARE  
ASSESSING IS IN THESE SLIDES.

WHAT WE'RE GONNA LOOK AT  
WHEN WE COME ON THE AUDIT

IS CONTAINED IN THE SLIDES.

SO AGAIN, POLICIES AND  
PROCEDURES THAT DESCRIBE

EXPECTATIONS, COMPLIANCE  
EXPECTATIONS FOR ALL OF YOUR

EMPLOYEES NEED TO BE CONTAINED

IN THESE POLICIES  
AND PROCEDURES,

THAT THEY CAN SHOW  
AND DEMONSTRATE HOW YOU

IMPLEMENT COMPLIANT  
OPERATIONS, THAT THE POLICIES

AND PROCEDURES DESCRIBE HOW  
ISSUES ARE INVESTIGATED,

RESOLVED, AND HOW THEY  
LEAD TO CHANGES IN POLICIES

AND PROCEDURES.

ONE NOTE. CMS CAN'T TELL  
YOU WHAT YOUR POLICIES

AND PROCEDURES  
SHOULD LOOK LIKE.

THEY REALLY SHOULD  
BE DIFFERENT

FOR EVERY ORGANIZATION.

BUT I CAN TELL YOU WHAT  
WE'RE GONNA BE LOOKING FOR,

AND THESE ARE THE THINGS WE'RE  
GONNA BE LOOKING FOR CONTAINED

IN THIS SLIDE.

THIS IS HOW YOU  
WILL BE ASSESSED.

ELEMENT NUMBER 2 IS THE  
DESIGNATION OF A COMPLIANCE

OFFICER AND A COMPLIANCE  
COMMITTEE.

WE'LL BE LOOKING FOR  
COMPLIANCE OFFICER ACCESS TO

THE BOARD ON AN  
INDIVIDUAL LEVEL.

WE'LL BE LOOKING FOR MEETING  
MINUTES THAT CAN REFLECT THAT.

SO SOMETHING THAT WILL  
DEMONSTRATE TO CMS THAT

A COMPLIANCE OFFICER HAS MET  
ROUTINELY WITH THE BOARD,

THAT IT'S DOCUMENTED, AND  
THAT THERE IS COMMUNICATION.

FINALLY, YOUR COMPLIANCE  
OFFICER MUST BE AN EMPLOYEE

OF THE ORGANIZATION.

IT CANNOT BE A CONSULTANT,  
A CONTRACTOR, OR SOMEBODY YOU

FOUND ON THE STREET.

WE WILL BE--ANOTHER THING I  
WILL BE LOOKING FOR WHEN WE

COME ON SITE IS INTERVIEWING  
BOARD MEMBERS TO VALIDATE THAT

THE POINT I MADE EARLIER ABOUT  
YOUR COMPLIANCE OFFICER HAVING

ACCESS TO THOSE PEOPLE.

WE WOULD LIKE TO BE ABLE  
TO INTERVIEW BOARD MEMBERS

AND SEE SOME SORT OF EVIDENCE  
THAT DOCUMENTS THAT THAT

PERSON, YOUR COMPLIANCE  
OFFICER, HAS ACCESS TO

THE SENIOR-MOST PEOPLE  
IN THE ORGANIZATION.

THERE WE GO.

ELEMENT NUMBER 3 IS THAT A  
PLAN SPONSOR MUST ESTABLISH,

IMPLEMENT, AND PROVIDE  
TRAINING AND EDUCATION.

SPECIFIC COMPLIANCE TRAINING  
AND EDUCATION NEEDS TO HAPPEN

AT THE TIME A PERSON IS HIRED,  
NEEDS TO HAPPEN ANNUALLY,

AND IT NEEDS TO  
HAPPEN FOR EVERYONE.

SO NOT JUST STAFF, BUT SENIOR  
EXECUTIVES IN ALL LEVELS

OF THE ORGANIZATION.

I DID WANT TO NOTE THAT THERE  
IS A FRAUD, WASTE, AND ABUSE

TRAINING REQUIREMENT,  
BUT AGAIN, THIS IS SOMETHING

THAT'S MANAGED OUT OF THE  
OFFICE OF PROGRAM INTEGRITY,

BUT THERE'S A REQUIREMENT THAT  
EVERYONE HAS TO HAVE FRAUD,

WASTE, AND ABUSE TRAINING ONCE  
A YEAR AND THAT ALL FIRST

TIER, DOWNSTREAM AND RELATED  
ENTITIES HAVE FRAUD, WASTE,

AND ABUSE TRAINING  
ONCE A YEAR.

AFTERWARD I CAN GIVE YOU  
SOME MORE INFORMATION

ABOUT THIS REQUIREMENT.

I KNOW IT CAME OUT AND NEEDED  
TO BE IMPLEMENTED BY

THE END OF 2009.

I CAN REFER YOU TO SOMEBODY  
THAT CAN HELP YOU WITH THIS

REQUIREMENT IF NEED BE, BUT IF  
YOUR FIRST TIER, DOWNSTREAM OR

RELATED ENTITIES HAVE PREVIOUSLY  
MET THE FEE FOR SERVICE FRAUD,

WASTE, AND ABUSE TRAINING  
REQUIREMENT THAT EXISTS,

GET PROOF OF THAT SO THAT THEY  
CAN BE DEEMED FOR HAVING MET

THIS OTHER REQUIREMENT.

AND AGAIN, WE CAN TALK ABOUT  
THAT IN MORE DETAIL LATER IF

ANYBODY IS INTERESTED OR I'D  
BE HAPPY TO REFER YOU TO

THE PERSON AT CENTRAL OFFICE  
WHO COULD HELP YOU

WITH QUESTIONS ON THAT.

ELEMENT NUMBER 4 HAS TO  
DO WITH ESTABLISHING

AND IMPLEMENTING EFFECTIVE  
LINES OF COMMUNICATION.

THIS ONE SOUNDS PRETTY  
STRAIGHTFORWARD IF YOU ASK ME.

THERE'S TWO AREAS THAT I  
THINK ARE MOST SIGNIFICANT

ABOUT THIS ELEMENT.

NUMBER ONE IS THAT THERE NEEDS  
TO BE ACCESS PROVIDED FOR ALL

EMPLOYEES TO REPORT ISSUES  
REGARDLESS OF THEIR POSITION

WITHIN THE ORGANIZATION.

THEY NEED TO HAVE THE ABILITY  
TO REPORT CONCERNS, WHETHER

THAT'S TO THE COMPLIANCE  
OFFICER, A MEMBER

OF THE COMPLIANCE COMMITTEE,  
A HOT LINE.

THERE NEEDS TO BE ACCESS FOR  
ALL EMPLOYEES, NUMBER ONE.

AND NUMBER 2, IT NEEDS TO BE  
ANONYMOUS AND CONFIDENTIAL.

### **Part 3**

>> ELEMENT NUMBER 5 HAS TO DO  
WITH DISCIPLINARY STANDARDS.

SO TO ME, THAT MEANS WHAT  
ARE YOUR EXPECTATIONS

FOR EMPLOYEES IN YOUR  
ORGANIZATION AROUND REPORTING

COMPLIANCE CONCERNS,  
NUMBER ONE.

NUMBER 2, WHAT ARE YOUR  
EXPECTATIONS FOR ETHICAL

AND PROPER BEHAVIOR OF  
EVERYONE IN YOUR ORGANIZATION?

AND THEN FINALLY, WHEN THOSE--  
IF AND WHEN THOSE EXPECTATIONS

ARE NOT MET, WHAT ARE  
THE CONSEQUENCES FOR EMPLOYEES

WHO ARE PERHAPS ENGAGING IN  
THAT BEHAVIOR, OR NUMBER 2,

EMPLOYEES WHO OBSERVE IT  
AND FAIL TO REPORT?

ELEMENT NUMBER 6 HAS TO  
DO WITH ESTABLISHING

AND IMPLEMENTING AN EFFECTIVE  
SYSTEM OF ROUTINE

MONITORING AND IDENTIFYING  
COMPLIANCE RISKS.

WE'RE ON NUMBER 6.  
WE'RE IN THE HOME STRETCH.

WHAT THIS MEANS TO ME, AGAIN,  
AND WHAT WE'LL BE ASSESSING IS

WHETHER OR NOT--IS YOUR ENTITY  
DOING INTERNAL AUDITING

AND MONITORING?

IT MAY OR MAY NOT SURPRISE YOU  
THAT ONE OF THE LARGEST HEALTH

PLANS THAT CMS CONTRACTS  
WITH--I WAS SHOCKED TO LEARN

ABOUT A YEAR AGO THAT THEY  
DIDN'T DO ANY INTERNAL

AUDITING OF THEIR OPERATIONS.

NOT A GOOD POSITION TO BE IN.

ARE YOU DOING A RISK  
ASSESSMENT TO IDENTIFY YOUR

ORGANIZATION'S OWN WEAKNESSES?

AND I SUSPECT THAT IF I TALK  
TO 10 PEOPLE IN THE ROOM,

I MIGHT GET 10 DIFFERENT  
ANSWERS ABOUT WHAT THOSE

WEAKNESSES MIGHT BE.

AGAIN, CMS DOES NOT WANT TO BE  
IN A POSITION TO TELL YOU WHAT

THIS NEEDS TO LOOK LIKE,  
WHAT THE ANSWER SHOULD BE.

WE JUST WANT TO SEE THAT  
YOU'VE IMPLEMENTED AND ADOPTED

THESE THINGS TO  
YOUR ORGANIZATION.

ARE YOU DOING THE  
SAME FOR CONTRACTORS?

SO AUDITING AND MONITORING  
YOUR CONTRACTORS OR ARE YOU

HAVING AN EXTERNAL  
AUDITOR COME IN AND LOOK

AT YOUR ORGANIZATION?

AND THEN FINALLY, ARE YOU  
EVALUATING THE PROGRAM,

YOUR COMPLIANCE PROGRAM,  
AS A WHOLE?

FINALLY NUMBER 7.

THIS ELEMENT HAS TO DO  
WITH PROMPT RESPONSE TO

DETECTED OFFENSES.

SO WHEN AN ISSUE COMES UP,  
ARE YOU TAKING ACTION

TO CORRECT IT?

THAT ONE'S PRETTY  
STRAIGHTFORWARD IF YOU ASK ME.

BE ABLE TO DEMONSTRATE TO CMS  
THAT WHEN SOMETHING HAS GONE

WRONG, YOU TOOK AN ACTION.

IT DIDN'T SORT OF LINGER IN  
THE PIPELINE OF THE COMPLIANCE

HOTLINE FOR A MONTH AND A  
HALF, WHICH IS SOMETHING ELSE

I'VE SEEN RECENTLY.

SHOW US THAT WHEN YOU FOUND  
AN ISSUE YOU DID

SOMETHING ABOUT IT.

THE OTHER SORT OF FOCUS,  
I THINK, OF THIS ELEMENT IS

THAT YOUR ENTITY NEEDS TO  
HAVE A PROCESS AND BE ABLE TO

DOCUMENT THE PROCESS TO  
SELF-DISCLOSE ISSUES TO CMS.

I'M OF THE OPINION THAT  
YOU COULD ARGUE EITHER WAY.

I MEAN,  
IT'S REALLY HARD TO ENCOURAGE

PEOPLE TO SELF-DISCLOSE  
ISSUES TO CMS BECAUSE IT'S

LIKE WALKING IN AND  
ASKING TO BE PUNISHED.

I REALIZE THAT.

BUT IT'S A WHOLE HECK OF A LOT  
BETTER TO BE HONEST AND UP FRONT

ABOUT ISSUES AND  
IT'S MUCH BETTER IF YOUR

ORGANIZATION IDENTIFIES  
AN ISSUE THAN IT IS

IF CMS FINDS OUT ABOUT IT  
AFTER THE FACT.

YOU KNOW, MY MOTHER USED TO  
TELL ME THAT IF YOU WOULD JUST

TELL ME THE TRUTH AND TELL ME  
WHAT YOU DID WRONG, YOU'LL GET

IN MUCH LESS TROUBLE THAN  
IF YOU TRY TO COVER IT UP

AND FIND OUT ABOUT IT LATER,

AND I THINK THAT STILL

HOLDS TRUE.

SO LET'S MOVE ON AND  
TALK ABOUT EFFECTIVENESS

FOR THE COMPLIANCE PROGRAM.

I HOPE YOU CAN SEE THIS.  
I THINK YOU CAN.

SO WHEN YOU TALK ABOUT  
EFFECTIVENESS OF A COMPLIANCE

PROGRAM, WE'RE GONNA BE  
LOOKING AT IT IN A VERY

SPECIFIC WAY, AND THAT IS TO  
TAKE THE 7 ELEMENTS AND SORT OF

THROW THEM UP AGAINST  
3 CONCEPTS, AND THOSE ARE

STRUCTURE, PROCESS,  
AND OUTCOMES.

AND THE NEXT COUPLE OF SLIDES  
ATTEMPT TO TAKE THE 7 ELEMENTS

AND SORT OF FRAME THEM WITHIN  
THESE 3 CONCEPTS OF STRUCTURE,

PROCESS, AND OUTCOMES,  
AND DESCRIBE HOW WE MIGHT

ASSESS IT WITH THOSE IDEAS.

SO HOW WILL CMS  
MEASURE EFFECTIVENESS?

WELL, NUMBER ONE HAS TO DO  
WITH LOOKING AT THE STRUCTURE

OF YOUR ORGANIZATION.

IF YOU LOOK AT THE BULLETS  
UNDERNEATH HERE, THESE REALLY

TIE IN VERY CLOSELY  
WITH THE 7 ELEMENTS--

SOME OF THE 7 ELEMENTS,  
I SHOULD SAY.

SO EDUCATION AND TRAINING,  
REPORTING MECHANISMS, POLICIES

AND PROCEDURES, IF YOU ASK ME,  
THESE REALLY HAVE TO DO

WITH THE STRUCTURE OF  
YOUR COMPLIANCE PROGRAMS.

THESE ARE THE FOUNDATION  
UPON WHICH YOUR COMPLIANCE

PROGRAM IS BUILT.

AND IF THESE ARE STABLE AND--  
WHAT'S THE RIGHT WORD

I'M LOOKING FOR--ROBUST, I  
THINK FRANKLY, THAT'S HALF

THE BATTLE.

LOOKING AT PROCESS,  
THIS REALLY IS

WHERE'S THE ACTIVITY?

HOW DOES YOUR  
COMPLIANCE PROGRAM WORK?

SO AGAIN, THESE ARE  
SORT OF TIDBITS OF SOME OF

THE 7 ELEMENTS  
THAT WE TALKED ABOUT.

AGAIN, HOW DOES  
YOUR SYSTEM WORK?

WHERE IS THE ACTIVITY?

DEMONSTRATE TO CMS WHAT YOUR  
ORGANIZATION ACTUALLY DOES

SO YOU DON'T JUST  
HAVE THE PLAN.

THIS IS MOVING  
BEYOND STRUCTURE.

MAYBE YOU HAVE SOME GREAT  
POLICIES AND PROCEDURES

IN PLACE, BUT SHOW ME  
WHAT YOU ACTUALLY DO.

SHOW ME YOUR RISK ASSESSMENT.

SHOW ME THAT YOU'VE RESPONDED  
TO DETECTED OFFENSES OR THAT

YOU'VE TAKEN DISCIPLINARY  
ACTION WHEN SOMEBODY HAS

VIOLATED ONE OF THE  
REGULATIONS OR PART OF YOUR

CODE OF CONDUCT.

AGAIN, WE WANT TO SEE  
IT IN PROCESS.

SHOW ME HOW IT WORKS.

AND THEN FINALLY, OUTCOMES.

WE WANT TO SEE WHAT IT DOES.

WHAT DOES YOUR COMPLIANCE  
PROGRAM DO?

SHOW ME WHAT IT'S BEEN ABLE  
TO PRODUCE, OR THE OUTCOMES.

CMS IS GOING TO ASK FOR  
YOUR INTERNAL AUDIT RESULTS.

SHOW ME WHAT YOU'VE DONE  
TO LOOK AT YOUR PROGRAM TO

EVALUATE IT AND SHOW ME  
THE RESULT OF THAT.

THE FOCUS OF THESE AUDITS  
IS GOING TO BE DEMONSTRATION

AND VALIDATION.

WHAT DOES  
EFFECTIVENESS LOOK LIKE?

IF YOU ASK ME, EVERY SINGLE  
ONE OF THE ASPECTS FEEDS INTO

THE OTHER SO THAT YOU'RE  
REALLY CONTINUALLY REFINING

YOUR COMPLIANCE PROGRAM.

IF IT WORKS AND IF IT'S DONE  
PROPERLY...I SAID TO SOMEONE

EARLIER, THERE'S REALLY  
NO SUCH THING AS

A COMPLIANCE SEASON.

I KNOW IN CMS WE HAVE  
APPLICATION SEASON AND THERE'S

SURVEILLANCE SEASON,  
OPEN ENROLLMENT.

THERE IS NO COMPLIANCE SEASON  
BECAUSE IT SHOULD NEVER BE

OFF SEASON.

WHAT'S THE RIGHT WORD FOR THAT?  
EVERGREEN?

COMPLIANCE IS EVERGREEN.  
IT NEVER GOES AWAY.

AT LEAST WE HOPE.  
PERENNIAL, THANK YOU.

I'M NOT A GARDNER.  
BUT THANK YOU.

THAT'S MUCH BETTER.

SO WRAPPING UP.

AGAIN, I WANT TO BE CLEAR THAT  
COMPLIANCE PROGRAMS, AND I  
THINK I'VE SAID THIS  
A BUNCH OF TIMES.

I FEEL LIKE I'M  
REPEATING MYSELF A LITTLE,

BUT COMPLIANCE PROGRAMS

AND EFFECTIVENESS

AND THE REQUIREMENTS OF THESE PROGRAMS, THIS IS NOT GONNA BE

ONE OF THOSE TOPICS WHERE CMS SAYS, "NEXT YEAR WE'RE GONNA

BE LOOKING AT XYZ" OR "THE NEXT TIME WE COME AND AUDIT YOU,

WE'RE GONNA TO BE DOING XYZ."

WE ARE DOING THIS.

THIS IS SOMETHING THAT WE'RE FOCUSING ON NOW.

SO YOU CAN EXPECT US

AND YOU CAN EXPECT THAT THIS WILL BE A FOCUS.

OIG, GAO, CONGRESS ARE ALL LOOKING AT CMS IN THIS AREA.

I HAD THE DISTINCT PLEASURE OF TALKING TO A SENATE

SUBCOMMITTEE A FEW WEEKS AGO, WHICH WAS ENTERTAINING,

ABOUT COMPLIANCE PROGRAMS AND THE QUESTION THAT THEY KEPT

ASKING ME WAS, "SO, MICHELLE, HOW MANY ARE YOU GONNA DO?"

"SO, MICHELLE, HOW MANY AUDITS ARE YOU GONNA DO?"

AND I CERTAINLY DID MY BEST TO HEDGE AND NOT COMMIT TO

A NUMBER, BUT EVENTUALLY I DID, TO THE EXTREME

DISAPPOINTMENT OF MY BOSS.

BUT YOU CAN EXPECT THAT WE WILL BE COMING.

WE'RE BEING AUDITED AND  
STUDIED AND LOOKED AT IN THIS

AREA VERY HEAVILY.

I DON'T KNOW WHY THE SENATE--  
WELL, I CAN TELL YOU WHY

THE SENATE CARES ABOUT THIS,  
BUT THIS IS A REALLY

HOT ISSUE.

SO IF CMS IS GETTING PRESSURE,  
YOU CAN ASSUME THAT WE'RE

GONNA BE VERY, VERY  
ACTIVE IN THIS AREA.

LIKE I SAID, THIS IS SOMETHING  
WE ARE LOOKING AT NOW.

AND WITH THAT, IF YOU HAVE  
ANY FURTHER QUESTIONS

ABOUT COMPLIANCE PROGRAM  
REQUIREMENTS, PLEASE FEEL FREE

TO CALL ME IN BALTIMORE.

OR E-MAIL ME.

I'LL BE HAPPY TO TAKE ANY  
QUESTIONS YOU HAVE, OR I THINK

WE HAVE A WHOLE SPEAKER PANEL  
COMING UP, WHERE WE'LL ALL BE

HAPPY TO ANSWER ANY  
OF YOUR QUESTIONS.

THANK YOU.