



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

Michelle Turano, Deputy Director, Program Compliance and Oversight Group

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 CONVINCE 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 GONG 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.