Large Family
Child Care Homes Manual
(January 2017)

For use with
COMAR 13A.18 - Large Family Child Care Homes
(as amended effective 7/20/15)

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.01 Inspections.

A. The office shall inspect each child care home:

(1) On an announced basis before issuing a certificate of initial registration or continuing registration; and

(2) On an unannounced basis, at least once within each 12-month period after the date that a certificate of initial registration or continuing registration was issued to the provider.

**INTENT:**

- To validate compliance with the large family child care home regulations, the Regional Office will conduct an announced inspection before an initial or continuing registration is issued.

- To validate ongoing compliance with the large family child care home regulations, the Office will conduct an unannounced inspection at least once every 12 months after the issuance of an initial or continuing registration and at least 30 days prior to the anniversary date.

**Note:**

- An announced conversion inspection may be conducted on the same day as the 2nd 12-month “initial registration” unannounced inspection; however, a separate ELIS report must be completed for each type of inspection. See “Establishing Anniversary Dates and Coordinating Inspections”.

- Routine unannounced inspections may be “piggybacked” onto monitoring visits as well as complaint investigations; however, a separate ELIS report must be completed for each type of inspection. See “Establishing Anniversary Dates and Coordinating Inspections”.

- During unannounced visits, oftentimes a large family child care home may not be available for inspection due to the absence of the provider, the provider is not currently providing care, or the family child care home is simply closed. For guidance in addressing these issues, see “Non Responsive Providers and Providers Not Providing Care”.

B. The provider or staff member shall permit inspection of all areas of the home by the agency representative during the provider's hours of operation.

**INTENT:** Under Maryland law, it is the duty of the Office to inspect each home to determine if the home and the child care program comply with large family child care regulations. The Provider must allow inspection of the home by Office licensing staff during approved program hours.

**INSPECTION REPORT ITEM:** “Inspections”
COMPLIANCE CRITERIA: The Provider allows inspection by OCC licensing staff at any time during the home’s approved hours of operation.

ASSESSMENT METHOD: An inspection is either permitted or not.

Notes:

- Except as noted under Regulation E below, if the Provider fails to permit inspection of the Provider’s home during approved hours of care, the Provider’s registration may be suspended or revoked. If entry to the home is refused, the Licensing Specialist should notify the Regional Manager, and the Regional Manager should notify the OCC Legal Enforcement Unit.
- If children are heard or seen on the premises and the Provider refuses entry of OCC staff, the Licensing Specialist must call the local police.
- During any inspection, if the Licensing Specialist hears sounds (for example, thumps, crying, child voices) coming from a part of the home not approved for child care, the Specialist should ask if there is anyone else present in the home and, if someone else is present, who that person is. If the person has not been reported to OCC as a resident of the home, the Specialist should observe the area where the person is located. The Specialist’s observations should be recorded in the Summary of Findings if the area is observed.
- All inspections must be conducted in a manner exhibiting good customer service. (see “Customer Service – Referenced in Manual”)
- All findings of compliance and noncompliance must be noted by the Licensing Specialist in the Electronic Licensing Inspection System (ELIS). If the system malfunctions for any reason, a paper inspection report must be used.
- “Non-compliances” and “Discussed” items are automatically summarized in the “Summary of Findings” in ELIS.
- The entire inspection report consists of the completed “Inspection Report” form and the “Summary of Findings.”
- The inspection report is emailed to the provider, or if applicable, sent by the U.S. Postal Service.
- The scope of an inspection shall be as follows:

  - Announced inspection of the Provider’s entire home shall be conducted for purposes of initial registration and resumption of service registration (i.e., registration at a new address or after a break in service).
  - Announced conversion inspections shall be confined to the areas approved for child care. However, if the registration certificate specifies that certain parts of the home (which may include the outdoor area) are restricted from use, the Licensing Specialist should verbally confirm to the Provider (and note as a comment in the inspection report) that those restrictions remain in effect.
  - Annual unannounced inspections shall be confined to the areas approved for child care. However, if the registration certificate specifies that certain parts of the home (which may include the outdoor area) are
restricted from use, the Licensing Specialist should verbally confirm to the Provider (and note as a comment in the inspection report) that those restrictions remain in effect.

➢ Follow-up inspections to determine if a previously cited noncompliance has been corrected shall be confined to the approved child care area(s) unless the noncompliance was observed in another part of the home (in which case, the inspection may include that part in order to determine if correction has occurred).

➢ Monitoring inspections conducted in accordance with “Compliance Agreements” shall be confined to the areas approved for child care unless components of the agreement (for example, maintaining capacity, non-access of certain individuals) require observation of other parts of the home.

➢ Complaint investigation inspections shall be confined to the approved child care areas unless the nature of the complaint (for example, an allegation of overcapacity, or an unreported resident, or violation of a non-access agreement) suggests that another area of the home may be involved. In that case, the Licensing Specialist shall inspect the entire home, and, if a follow-up inspection is required, the entire home may also be inspected at that time.

C. The agency representative may make inspections, in addition to the announced and unannounced inspections specified in §A of this regulation, without prior notice to the provider.

**INTENT:** To determine if all children in care are safe and receiving proper care and supervision, Office licensing staff may make an unannounced inspection of the Provider’s home at any time during the home’s approved hours of operation.

D. Upon request, the provider or staff member shall make the records required by this subtitle available to the agency representative for inspection and copying.

**INTENT:** The Provider must allow Office licensing staff to inspect all records maintained in connection with the child care program and, if necessary, to remove any record from the home temporarily in order to copy it.

**INSPECTION REPORT ITEM:** “Inspections”

**COMPLIANCE CRITERIA:**

- All records are freely available for inspection by Office licensing staff.
- Upon request, the Provider release a record temporarily for copying.

**ASSESSMENT METHOD:** Records are either made available or not.
E. A provider or staff member may request satisfactory identification from the agency representative before admitting the person for an inspection.

**INTENT:** For the Provider’s own protection and the protection of residents and the children in care, the Provider may ask Office licensing staff for identification before permitting entry to the Provider’s home.

**Notes:**
- At all times while on duty, each Office licensing staff member shall carry and be prepared to display valid State of Maryland employee identification.
- If an Office staff member cannot or will not produce valid State of Maryland employee identification, the Provider may deny the staff member entry to the home.

F. A provider may appeal a finding of noncompliance with this subtitle by requesting a review of findings by the regional office or the central office of the Agency.

**INTENT:** If the Provider believes that a finding of noncompliance was wrong or unfair, the Provider may ask for a review of that finding by Office of Licensing management staff.

**Notes:**
The following are the steps for appealing a finding of noncompliance:
- Upon completion of the inspection, the Provider checks the box on the first page of the ELIS “Summary of Findings,” indicating that a review of findings is requested, or make the request to the Regional Office, via writing or email, within 30 days of the inspection.
- The Licensing Specialist notifies the Regional Manager/designee of the request.
- The Regional Manager/designee reviews the inspection data in ELIS and sends a letter to the Provider outlining the findings of the review.
- If the Provider requests a meeting and at that meeting the issues are not resolved, the Regional Manager/designee contacts the Program Manager of the OCC Licensing Branch.
- Instead of agreeing to meet with the Regional Manager/designee, the Provider may choose to contact the Licensing Branch Program Manager directly. In this event, the Regional Manager/designee shall:
  - Give the Provider the name and telephone number of the Program Manager, and
  - Call the Program Manager to summarize the situation, provide pertinent background information, and present the recommendation of the Regional Office.
.02 Complaints.
The office shall investigate:
A. Both written and oral complaints that relate to a potential violation of a regulation under this subtitle, including anonymous complaints; and

**INTENT:** As the agency responsible for regulating the large family child care home programs and assessing their compliance with child care regulations, the Office must investigate all complaints of regulatory violations. Any person may file a complaint, and the complaint may be verbal or written.

**Notes:** Complaints alleging a violation of large family child care home registration laws or regulations are handled in the following manner:
- The Regional Office accepts complaints that are filed in person, telephonically, or in writing by letter, fax, or e-mail.
- A complainant does not need to identify him/herself. Anonymous complaints are accepted.
- At the time it is received at the Regional Office, each complaint is classified as “Priority One” or “Priority Two”, based on the seriousness of the complaint allegations.
  - Investigation of Priority 1 complaints must be initiated within 48 hours.
  - Investigation of Priority 2 complaints must be initiated within ten (10) business days.
- Complaints are recorded by the Regional Office on a Complaint Intake form in the Child Care Administrative Tracking System (CCATS). A Provider may review a Complaint Intake form completed for a complaint filed against the home (although all material, if any, related to Child Protective Services must be redacted by the Regional Office).
- Complaint inspection/investigation results are recorded by the Regional Office in the Electronic Licensing Inspection System (ELIS).
- After the complaint investigation is finished, the complaint and the investigation findings are summarized on a Record of Complaint form in the Child Care Administrative Tracking System (CCATS).
- Upon receipt of a written Public Information Act (PIA) request, the summary of an unconfirmed or confirmed complaint may be released to:
  - The person making the complaint,
  - A parent whose child was enrolled at the child care center, or
  - A parent or business that currently uses (or is considering using) the child care center.
- Any information related to Child Protective Services must be redacted by the Regional Office prior to releasing the Record of Complaint in response to a PIA request.
- Complex PIA requests or PIA requests from Attorneys must be referred to the Office of the Attorney General for processing.
B. Complaints of unregistered family child care.

**INTENT:** Unless exempt by Maryland law from having to become registered, a person who provides unregistered family day care is violating the law. The Office is responsible for investigating all complaints of unregistered care to determine if a violation has been committed.

**Note:** See “Guidelines for Investigating Complaints of Unregistered or Unlicensed Child Care”

.03 Warnings.

If an investigation of a complaint or an inspection of a child care home indicates a violation of this subtitle that does not present an immediate threat to the health, safety, and welfare of a child in care, the office may issue a warning in writing, on an inspection report or by separate letter, that states:

A. The violation found, citing the regulation;
B. The time period for correcting the violation; and
C. That failure to correct the violation may result in sanctions being imposed or in suspension or revocation of the registration.

**INTENT:** A warning serves notice that the Provider have failed to comply with one or more child care regulations and that corrective action must be taken within a certain amount of time. Failure to make the correction may result in some enforcement action against the registration.

.04 Intermediate Sanctions.

A. Upon determining that a provider has violated or a child care home fails to meet any of the regulations of this subtitle, the office may:
   (1) Restrict the age or number of children accepted for care;
   (2) Reduce the number of children in care;
   (3) Require the provider to receive remedial instruction in a specified content area;
   (4) Increase the frequency of monitoring of the home during a specified period of time;
   (5) Enter into an agreement with the provider detailing requirements in addition to those above, including time limits for compliance; and
   (6) Notify, or require the provider to notify, a parent of a child who may be affected by the situation for which a sanction has been imposed.

**INTENT:** As an alternative to suspending or revoking the Provider’s registration, the Office may pursue an intermediate sanction which places certain limits or conditions on the operation of the Provider’s child care program. An intermediate sanction (voluntary or involuntary) should be seen as an opportunity for the Regional Office to work closely with the Provider to help bring the Provider’s child care program into full compliance.

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- An intermediate sanction may be voluntary on the part of the Provider, or involuntary:
  - Voluntary – for example, a compliance agreement
  - Involuntary – for example, the Regional Office imposes a reduction in capacity or a limitation on the number or ages of children the provider may admit for care
- Involuntary sanctions carry appeal rights, but voluntary sanctions do not. For additional information on “appeals” refer to the following:
  - “Request for Hearing/Appeal” form, OCC 1281
  - COMAR 13A.18.15, Administrative Hearings
- A limitation on admission of children or a reduction in capacity may be imposed immediately on an emergency basis if deemed necessary to protect children from imminent harm.
- A voluntary compliance agreement must be in writing, signed by the Provider and the Regional Office representative, and include a statement of:
  - Facts about the noncompliant situation that resulted in the agreement,
  - The respective responsibilities of the Provider and the Regional Office under the agreement, and
  - The consequences to the Provider of failing to observe the terms of the agreement.
  - The timeframe in which the compliance agreement will be in effect.

B. If the office determines that the provider has violated a condition or requirement of the intermediate sanction, the office may suspend or revoke the registration.

**INTENT:** The Provider is expected to abide by all the terms of the agreement. Failure to do so may result in suspension or revocation of the Provider’s registration.

0.05 Nonemergency Suspension.

A. The office may suspend the certificate of registration, for a period of not more than 60 calendar days, upon determining that the provider or the child care home is in violation of any of the regulations under this subtitle and that the health, safety, or welfare of a child in the home is threatened.

**INTENT:** To protect the safety and health of children in care, the Office may move to close the home temporarily to allow the Provider an opportunity to correct the violation or situation that poses a threat to the children.

B. The office shall notify the provider in writing of the suspension at least 20 calendar days before the effective date stating:
   (1) The effective date and period of the suspension;
   (2) The reason for suspension;
   (3) The regulation with which the provider has failed to comply that is the basis for the suspension;
(4) Corrections required to ensure reinstatement of the certificate of registration;
(5) That the provider shall stop providing child care on the effective date of the
suspension unless the provider requests a hearing;
(6) That the provider is entitled to a hearing if requested in writing within 20 calendar
days of the delivery of the notice;
(7) The procedure to be used if the provider wishes to request a hearing to appeal the
decision of the office;
(8) That the suspension shall be stayed if a hearing is requested;
(9) That, if the suspension is upheld following the hearing, the provider shall cease
providing child care for the period of the suspension;
(10) That the suspension may lead to revocation; and
(11) That the provider is required to surrender the certificate of registration to the
office when the suspension becomes effective.

INTENT: Under due process requirements, the Office must notify the Provider in
writing of the reasons for/details of the suspension, and inform the Provider of the
Provider’s appeal rights and how those rights may be exercised.

Notes:
• If the Provider requests a hearing within the required timeframe, the suspension
does not begin until after the hearing decision. Until that time, the Provider may
continue to operate. If the suspension action is upheld, the Provider must cease
providing care until the Office determines that the children in care are no longer
threatened.
• For additional information, refer to the following:
  ➢ “Request for Hearing/Appeal” form, OCC 1281
  ➢ COMAR 13A.18.15, Administrative Hearings
• A non-emergency suspension may be imposed when the provider fails to comply
with regulations and a potential risk to the health, safety, or welfare of children in
care is presented. Examples include (but are not limited to):
  ➢ Failure to report a new resident,
  ➢ Unauthorized use of a substitute (or use of an unapproved substitute), and
  ➢ Failure to correct non-compliances as required by the Office.
• A suspension may also be used if temporary closure of the program is in the best
interests of children in care. Examples include (but are not limited to):
  ➢ The home must be renovated or modified for health or safety purposes, and
closure will allow those changes to occur, and
  ➢ Illness or incapacitation of the provider.

C. The office shall notify the parents of the children in care of the suspension.

   INTENT: Parents must be informed of the suspension so that they can make other child
care arrangements

D. By the end of the suspension period, the office shall:
(1) Reinstatethe certificate of registration and return it to the provider; or
(2) Revoke the certificate of registration.

**INTENT:** Within 60 days after the suspension, the Office will determine if the violation(s) leading to the suspension have been sufficiently corrected, and either permit the Provider to re-open the Provider’s home, or move to revoke the Provider’s registration.

.06 **Emergency Suspension.**

A. The office may immediately suspend the certificate of registration for a period of not more than 45 calendar days upon finding that a child's health, safety, or welfare imperatively requires emergency action.

**INTENT:** Upon determining that there is imminent danger to the children in care, OCC may close the Provider’s home immediately.

**Notes:**

- Emergency suspensions are generally used in cases of child abuse or injurious treatment, criminal involvement, gross overcapacity or lack of supervision, violation of a non-access agreement, failure to provide access to the day care home during operating hours, or accidental injury to a child in care.

- Emergency suspensions may also be used during outbreaks of certain communicable diseases, environmental hazard cases such as failed septic systems, and other instances where children’s safety is immediately threatened and there is no alternative to immediate closure.

B. The office shall hand-deliver a written notice to the provider informing the provider of the emergency suspension, giving the reasons for the action, and notifying the provider of the right to request, within 30 days of the delivery of the notice, a hearing before the Superintendent's designee.

**INTENT:** In accordance with due process requirements, the Office must notify the Provider about the reason(s) for the suspension, the Provider’s right to appeal the suspension, and how to exercise that right.

**Note:** For additional information, refer to “Request for Hearing/Appeal form OCC 1281” and “COMAR 13A.18.15 - Administrative Hearings”

C. When the certificate of registration is to be suspended immediately:
(1) The office shall repossess the certificate of registration;
(2) The provider shall stop providing child care immediately; and
(3) The office shall notify the parents of the children in care of the suspension and make every reasonable effort to assist the parents of the children in making
other child care arrangements.

**INTENT:** Due to the urgency of the situation, the Office must ensure that the Provider ceases care immediately. Emergency suspensions take effect immediately upon delivery of the emergency suspension notice to the Provider and may last for up to 45 calendar days. To minimize disruption to the families of children in care, the Office shall assist parents to find alternate care arrangements.

**Notes:**

- Once the decision is made to conduct an emergency suspension, the Regional Manager/designee notifies the local Child Care Resource Center (CCRC) of the imminent emergency suspension. This allows the CCRC to be prepared to assist parents in finding alternate child care.
- As soon as the suspension action is taken, the Licensing Specialist compiles a list of names and addresses of all the parents of children in care.
- The Licensing Specialist hand delivers the suspension letter to parents arriving at the home to pick up children, or the Regional Manager sends the suspension letter by regular mail to each parent reporting that:
  - The family registration has been suspended,
  - The Provider may appeal the suspension,
  - The Provider must immediately stop providing care, and
  - The parent may contact the local CCRC for assistance.
  If the action is appealed, another letter is sent to each parent as soon as the appeal has been decided to let the parent know the outcome of that decision.

D. If a hearing is requested by the provider, the Superintendent's designee shall hold a hearing within 7 calendar days of the date of the request.

**INTENT:** The Provider has the right to a timely hearing of an appeal.

E. Within 7 calendar days of the hearing, a decision concerning the emergency suspension shall be made by the Superintendent's designee.

**INTENT:** The Provider has the right to a timely decision of the appeal.

F. If the decision does not uphold the emergency suspension, the provider may resume providing child care.

G. By the end of the suspension period, the office shall:
   (1) Reinstatethe certificate of registration and return it to the provider; or
   (2) Revoke the certificate of registration.

.07 Revocation.

A. The office may revoke a certificate of registration if the:
(1) Provider or child care home is in violation of one or more of the regulations under this subtitle and the health, safety, or welfare of a child in the home is threatened;

(2) Provider misrepresented or offered false information on the application or on any form or report required by the office;

(3) Provider interferes with or obstructs the agency representative in the performance of the duties of the office;

(4) Provider fails to submit all documentation required to maintain the certificate of registration;

(5) Provider or staff member refuses to permit access to a child or to the space in the home used for child care by a parent or an agency representative during operating hours of the child care home;

(6) Terms or conditions of a sanction have been violated;

(7) Violations required to be corrected during a period of suspension have not been corrected and the period has ended;

(8) The provider fails to comply with the:
   (a) Prohibitions on the use of an individual as an employee or a volunteer as set forth in COMAR 13A.18.06.03A — B and F, and .10B; or
   (b) Child security requirements set forth in COMAR 13A.18.07.06;

(9) Provider permits an individual to have child supervision responsibilities after being notified by the office that the individual has been disapproved for that purpose;

(10) Evaluation of information provided to or acquired by the office indicates that the provider is unable to care for the welfare of children; or

(11) Provider admits a child for treatment foster care in the home, unless the child is placed in the home in a preadoptive capacity.

**INTENT:** Revocation of the registration may occur if the Provider has demonstrated an inability or unwillingness to comply with large family child care home regulations, or if the Provider or a circumstance involving the Provider’s home presents a threat to children in care.

**Notes:**

- Revocation often follows a period of emergency suspension.
- A revocation becomes effective 20 calendar days after notification of revocation.
- If the revocation action is appealed, the revocation is stayed until the Office of Administrative Hearings (OAH) has heard the appeal and made a decision. If the revocation action follows an emergency suspension, the home must remain closed until OAH has reached a decision on the appeal.
- See “Request for Hearing/Appeal Form OCC 1281” and COMAR 13A.18.15, Administrative Hearings” for requirements pertaining to the appeal hearing process under the Office of Administrative Hearings (OAH).
B. If the office decides to revoke a certificate of registration, the office shall notify the provider in writing at least 20 calendar days in advance of the revocation, stating:

1. The effective date of the revocation;
2. The reason for the revocation;
3. The regulation with which the provider has failed to comply that is the basis for the revocation;
4. That the provider shall stop providing child care on the effective date of the revocation;
5. That the provider is entitled to a hearing if requested in writing within 20 calendar days of the delivery of the notice;
6. The procedure to be used if the provider wishes to request a hearing to appeal the decision of the office;
7. The revocation shall be stayed if the hearing is requested, unless the revocation immediately follows an emergency suspension period; and
8. That the provider is required to surrender the certificate of registration to the office when the revocation becomes effective.

**INTENT:** In accordance with due process requirements, the Office must notify the provider of the reason(s) for the revocation, the provider’s right to appeal the revocation action, and how that right may be exercised.

**Notes:**

- If the revocation action is appealed, the revocation is stayed until the Office of Administrative Hearings (OAH) has heard the appeal and made a decision. If the revocation action follows an emergency suspension, the home must remain closed until OAH has reached a decision on the appeal.
- See “Request for Hearing/Appeal Form OCC 1281 and COMAR 13A.18.15, Administrative Hearings” for requirements pertaining to the appeal hearing process under the Office of Administrative Hearings (OAH).
- If the revocation action is upheld by OAH at the appeal hearing, the Provider must immediately surrender the large family child care home registration to the Regional Office.

C. The office shall notify the parents of the children in care of the revocation.

**INTENT:** Parents need to know about the revocation action so they can make an informed decision about whether to leave their children in care at the home if it is allowed to remain open pending an appeal hearing. They must also be notified so that they can make suitable alternate child care arrangements if they wish.

**Notes:**

- Parents are notified of the revocation action as follows:
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- As soon as the revocation action is taken, the Licensing Specialist compiles a list of names and addresses of all the parents using the child care program.
- The Regional Manager sends a letter by regular mail to each parent reporting that:
  - The registration has been revoked,
  - The provider may appeal the revocation, and
  - The provider may remain in operation until the appeal is concluded.
- If the action is appealed, another letter is sent to each parent as soon as the appeal has been decided to let the parent know the outcome of that decision.

.08 Penalties.

A. An individual found to be operating a child care home, or advertising a family child care service, without a valid family child care registration is guilty of a misdemeanor and on conviction is subject to a fine not exceeding:
   (1) $1,500 for the first violation; and
   (2) $2,500 for a second or subsequent violation.

B. The office may institute legal proceedings to:
   (1) Enjoin any individual not registered who is providing family child care from continuing to operate; or
   (2) Ask a court in the jurisdiction of the child care home to impose a fine of up to the maximum amount permitted by law on an individual found to be operating in violation of this subtitle.

**INTENT:**

- Operation of a large family care home without a certificate of registration is a misdemeanor and fines may be imposed. The Office can request the issuance of a criminal summons against an alleged unregistered provider by filing an application for statement of charges with the court commissioner in the District Court. If the provider is found guilty of the misdemeanor charge, a criminal fine may be imposed for each occurrence.

- If an unregistered provider continues to operate in violation of a court injunction, the court may impose a fine.

.09 Civil Citations.

A. The office may issue a civil citation imposing a civil penalty to an individual who provides unregistered family child care in violation of the requirements of this subtitle.

**INTENT:** Maryland law establishes civil penalties for operating an unregistered family
child care home. These civil penalties are imposed through issuance of civil citations by the Office.

B. Assessment of Penalty.
(1) Subject to §B(3) of this regulation, an individual to whom a civil citation is issued is subject to a civil penalty in the amount of:
   (a) $250 for the first violation;
   (b) $500 for the second violation; and
   (c) 1,000 for the third and each subsequent violation.
(2) Each day that unregistered family child care occurs in violation of the requirements of this subtitle is a separate violation under this regulation.
(3) The total amount of civil penalty imposed against an individual in an action under this regulation may not exceed $5,000.

   INTENT: Increased penalties for continued violations of the law are intended to discourage those violations.

C. An individual against whom a civil penalty has been imposed under this regulation shall pay the full amount of the penalty promptly to the Department, as instructed by the civil citation or as otherwise directed by the office.

   INTENT: The full amount of a penalty must be paid when and as specified.

D. Appeals.
(1) An individual may appeal the imposition of a civil penalty under this regulation by filing an appeal with the office as instructed by the civil citation or as otherwise directed by the office.
(2) Appeals are conducted in accordance with the provisions of COMAR 13A.18.15.

   INTENT: An individual who has been issued a civil citation may appeal the assessed penalty. The appeal shall be processed and heard according to procedures established by State regulation.